HOFFRICHTER
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For device types
9LV103 and 9LV203

CARAT I pro
CARAT II pro

Ventilator

Service manual

for providers and service technicians

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Please ensure that you are always working with the most current version of this service manual. Should you have any questions, please contact the ventilation device provider, or check our information at www.hoffrichter.de.

The respiratory device may only be operated and maintained by trained personnel.

The following documents are available for CARAT II pro in addition to this service manual:

- User's manual CARAT I/II pro for physicians and medical professionals
- User's manual for CARAT I/II pro for patients
- Brief instructions for CARAT I/II pro
- Hygiene concept
- Maintenance plan

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CHAPTER 1
INTRODUCTION

This service manual is directed towards providers and service technicians for performing maintenance and repair work on CARAT I pro and CARAT II pro ventilators.

1.1 SYMBOLS USED IN THIS SERVICE MANUAL

Important information is denoted by symbols in this service manual. Be sure to follow these instructions in order to avoid accidents, personal injury and material damage.

In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.

This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

⚠CAUTION
This symbol denotes hazardous situations that may lead to light or severe injuries.

NOTICE
This symbol denotes information, tips and instructions for the efficient, correct use of the device.

1.2 SAFETY INFORMATION

- Before you start with the maintenance, fully read and understand the contents of this Service Manual.
- There is a danger of short-circuiting of the capacitors and battery, even when no electrical power is applied to the device. If the main switch is switched off and the power supply is connected, the internal battery is charged, electrical power is still applied to the device!
- Repair and maintenance tasks may only be carried out by suitably qualified, authorized and competent personal.
- FiO_2 sensors contain a caustic liquid. Avoid skin or eye contact if there is a sensor leak!
- For FiO_2 sensors no adjustment or repair work is required.
- Components carrying oxygen must not come into contact with oils or fats. There is a risk for fire and explosion.
- For hygienic reasons, it is recommended to wear disposable gloves when you carry out a task on the device. Before the next tasks, please wipe the device with a commercial disinfecting solution, e.g. Mikrozid® Liquid.
- The documents delivered with the device must be checked when the device arrives at the Service department. Should anything point to contamination of the device (e.g., MRSA), this device should be treated separately, according to the CARAT pro hygiene concept (transport, storage, processing).
- Special hygienic measures are necessary when a maintenance or repair task is carried out on a machine contaminated by MRSA (Methicillin Resistant Staphylococcus Aureus). In all circumstances, protective clothing must be worn, such as gloves, lab coat and face mask. Please refer to the CARAT pro hygiene concept for further information on the handling of MRSA-contaminated devices

1.3 MAINTENANCE, REPAIR, HYGIENIC RECONDITIONING AND SAFETY-RELATED CHECK

NOTICE
All procedures performed are to be documented.

1.3.1 MAINTENANCE

The ventilator is to be serviced only by authorized service companies. Servicing intervals, as outlined in the maintenance schedule, must be observed.

1.3.2 MAINTENANCE SCHEDULE

Table 1: Service intervals - overview

When?	What?	By whom?
Before commissioning	Safety-related check	Provider/Service
Weekly	Clean/replace the coarse filter	User
	Visually check of the fine filter	User
Monthly, or before, if heavily contaminated	Replace fine filter	User
Every 6 months	Battery quick test	User/Provider
Every 6 months during in storage	Charge battery to 100 %	User/Provider
Every 6 months without bacterial filter	Replace the valve membrane (expiration)	Provider/Service
Every 12 months	Maintenance 1	Provider/Service
	Safety-related check	Provider/Service
Every 2 years	Maintenance 2	Provider/Service
After 15,000 h blower run time or every 5 years	Maintenance 5	Provider/Service

Complimentary activities	What?	By whom?
If patient has changed, reconditioning, recondition contaminated devices	Hygienic reconditioning, manually or with the KR1000 (Keredusy) procedure	Provider/Service
MRSA contaminated devices	Hygienic reconditioning using the KR1000 (Keredusy) process	Provider/Service

1.3.3 REPAIR WORK

Repairs to the device may only be carried out by an authorized service agency.

The following should be carried out in the case of a repair:

1. Wipe disinfect the device surface e.g. schülke wipes [or local equivalent]
2. Check the error description and error analysis
3. Performing the repairs
4. Final inspection
5. Packing the device according to packaging instructions
6. Shipping according to the shipping instructions (see Page 81)

1.3.4 HYGIENIC RECONDITIONING

During recondition, recondition on changing patients, as well as recondition after contamination (e.g., MRSA), the device should be treated according to the CARAT pro hygiene concept.

CHAPTER 2
DEVICE DESCRIPTION

2.1 GENERAL DEVICE DESCRIPTION

CARAT pro is used for continuous or intermittent respiratory support and for the ventilation of patients. The device is suitable for adults and children with a tidal volume of 50 ml and higher and is designed home or clinical applications.

CARAT pro has pressure- and volume-controlled ventilation modes. The ventilation can be invasive (e.g using a tracheostoma) or non-invasive (using a mask). CARAT pro has the technical prerequisites allowing it to run with a single line patient circuit with exhalation valve (CARAT I pro and CARAT II pro) or with a double line patient circuit (CARAT II pro) as required.

The device can be connected to a low-pressure source of oxygen for ventilation with increased oxygen concentration. There is also the option of combining CARAT pro with an external humidifier.

2.2 CONNECTIONS AT THE FRONT OF THE DEVICE

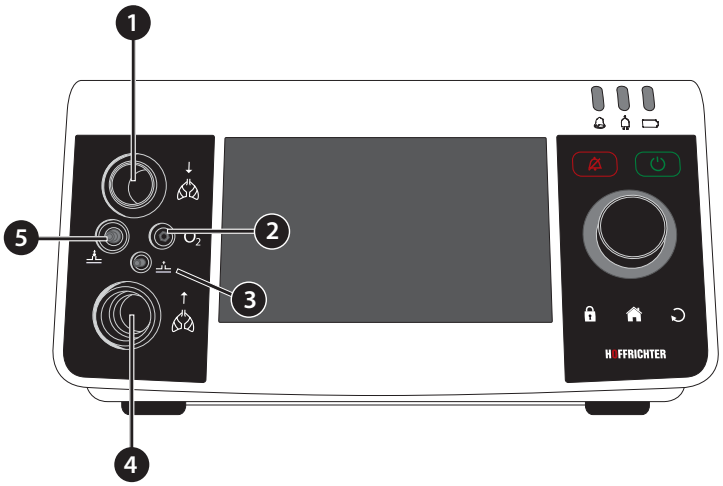


Figure 1: Connections at the front of the device

1 Connection of tube circuit - inspiration
The single line patient circuit or the inspiration section of a double line patient circuit are connected here.

2 O_2 Connection of FiO_2 sensor cable
Connect the FiO_2 sensor cable here for measuring the oxygen concentration.

3 Connection of pressure measuring tube
The pressure measuring tube is connected here. (Only when using a tube circuit with pressure measuring tube.)

4 Connection of tube circuit - expiration
The expiration section of a double line patient circuit is connected here.

5 Connection of control tube

2.3 CONNECTIONS ON THE REAR SIDE OF THE DEVICE

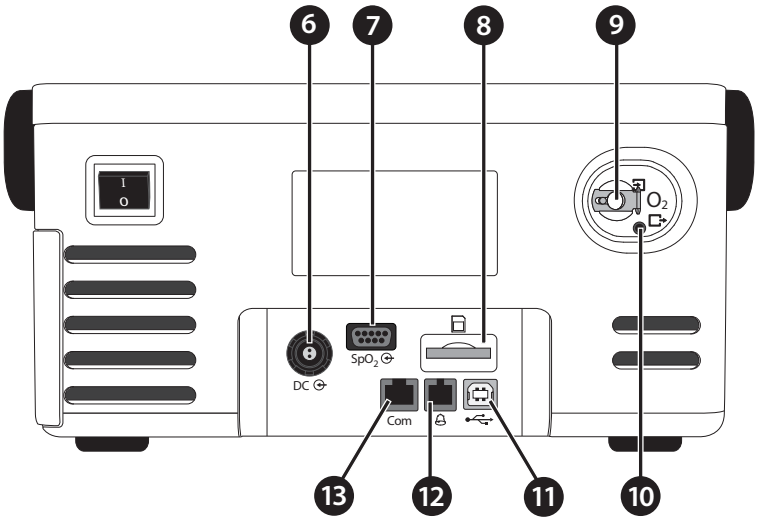


Figure 2: Connections on the rear side of the device

6 DC DC connection

The power supply plug is connected here.

7 SpO2 Connection of SpO_2 sensor

A SpO_2 sensor can be connected here.

8 SD card slot

An SD card here can be inserted here.

9 O2 FiO_2 connection (Low-pressure connection: ≤ 1000 hPa, ≤ 5 l/min)

During oxygen input the oxygen source is connected here. Use the supplied oxygen connection adapter for that purpose.

10 O2 FiO_2 output

Oxygen monitoring:
This is the exit for excess oxygen from the oxygen valve of the unit, when ventilation has been turned off.

Pressure monitoring:
Excess oxygen pressure is exhausted to the outside from this exit during oxygen therapy. This is the case, when the pressure is higher than 1 hPa above the pre-set ventilation pressure setting. In the volume controlled mode, the valve also opens when the measured breathing volume is more than 10 % higher than the pre-set value.

11 USB interface (Connection of PC)

A PC may be connected here with a USB cable (optional accessory). In order to be able to communicate with the device, the PC software "EASYset" has to be installed on the PC.

12 Connection of remote alarm/nurse call

An alarmbox (optional accessory) or a nurse call system may be connected here.

13 Com RS232 interface (service interface)

Accessories connectionControl elements

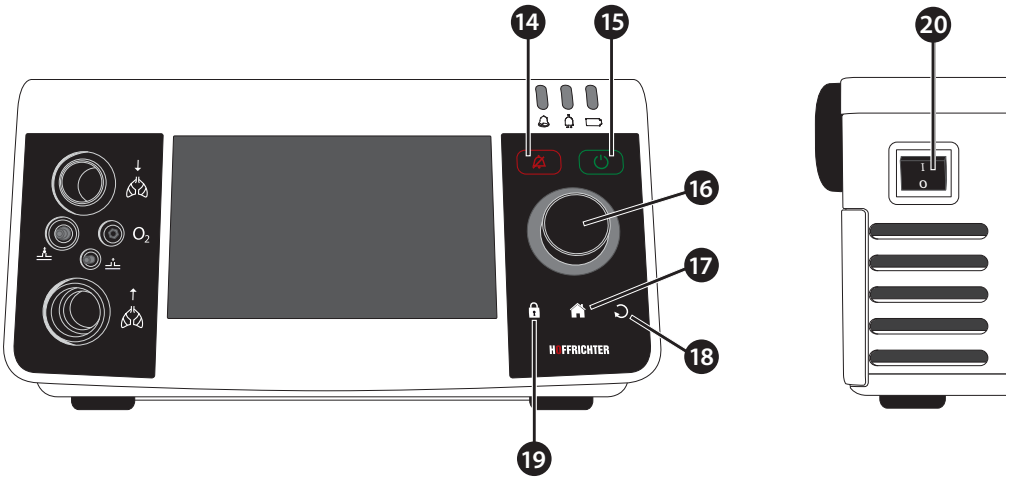


Figure 3: Control elements

14 Alarm key

The alarm button has several functions:

Function	Condition	Action
Confirm all current alarms	Active alarms	Press briefly
confirm no longer active alarms	Stored alarms	Press briefly
Mute the audible alarm for 2 min (audio alarm pause)	Active alarms	Press briefly
Cancel the audible alarm suppression	Audio alarm paused	Press briefly

When multiple events occur at the same time, only one event is confirmed each time the button is pressed and in the order they are listed above.

15 ON/OFF key

Function	Action
Start ventilation	Press briefly
Stop ventilation	Press (MFK) briefly and confirm with "Yes"

16 Multifunction key MFK

Function	Action
Select another parameter	Turn
Set parameters	Turn
Confirm parameter selection	Press briefly
Confirm modified parameter value	Press briefly
Open settings window for curves and loops in the monitoring screen	Press briefly

The MFK is backlit (only when "MFK brightness" > 0 %). The color of the light depends on the operating status or the alarm priority of the currently displayed alarm. The backlight intensity of the MFK can be adjusted in the system screen.

17 Home key

Function	Action
Return to the home screen	Press briefly

18 Escape key

Function	Action
Exit the current screen	Press briefly
Leave selected parameter	Press briefly
Cancel	Press briefly

19 Safe key

Function	Action
Activate key lock	Press briefly and confirm with MFK
Deactivate key lock	Press briefly and confirm with MFK

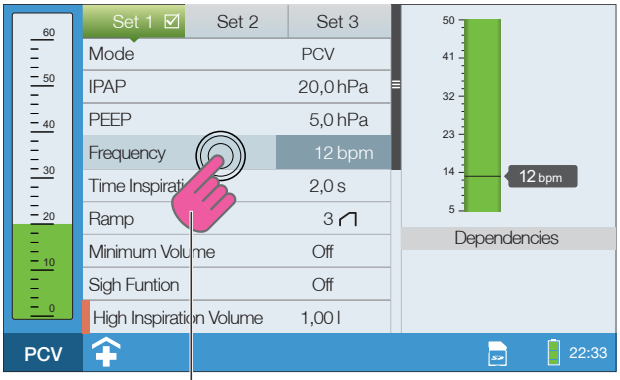
20 Main switch

Switch the device on and off with the main switch.

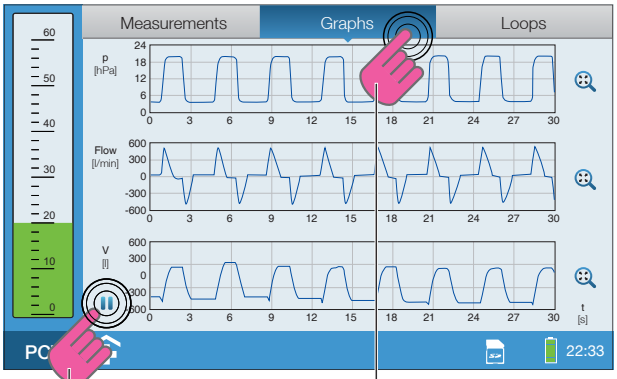
2.3.1 TOUCH SCREEN OPERATION

The following operations can be initiated with the touch screen:

Screen selection

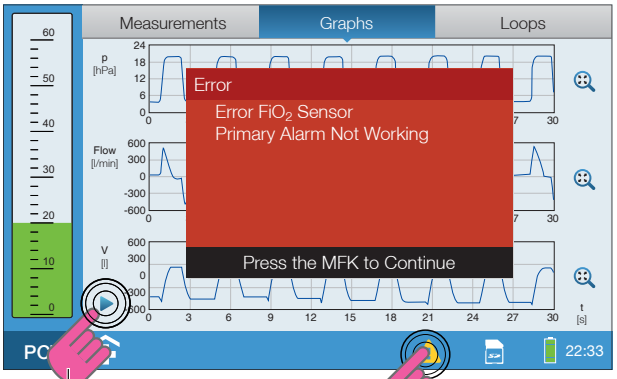


Parameter selection



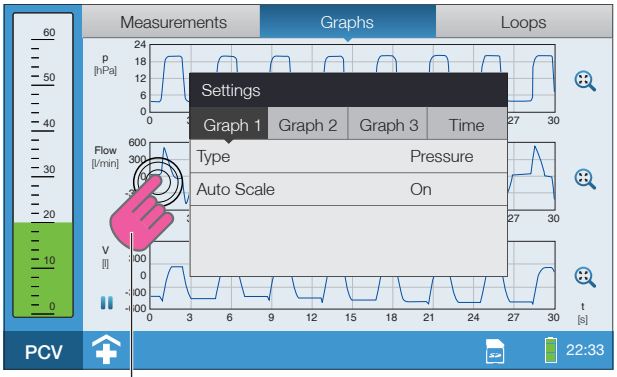
Freeze real-time curve on the monitoring screen

Select tab

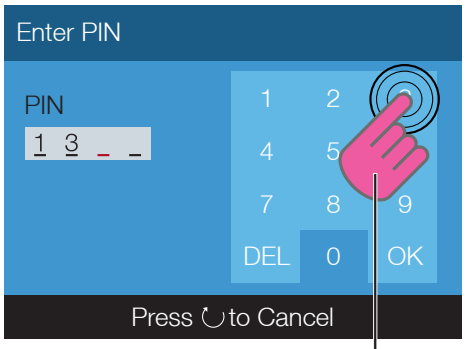


Continue real-time curve on the monitoring screen

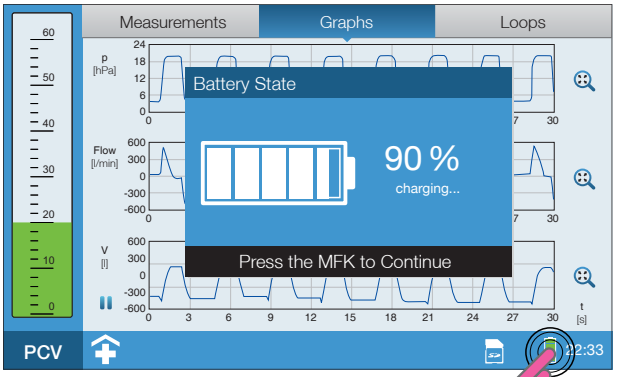
Show errors (if present)



Open settings window



Enter the PIN



Show battery state

2.4 LED DISPLAYS

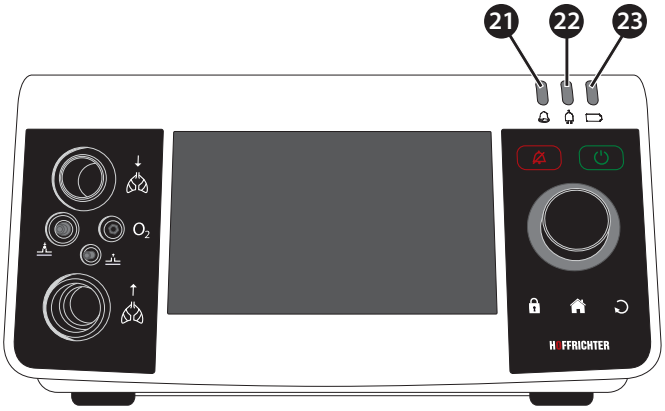


Figure 4: LED Displays

21 Alarm LED

The alarm LED lits/flashes in the event of an alarm. It also provides information on the alarm priority.

Color	Status (light)	Priority
Red	Flashes	HIGH
Yellow	Flashes	MEDIUM
Turquoise	Glows steadily	LOW

22 Power LED

The power LED gives information about the status of the power supply.

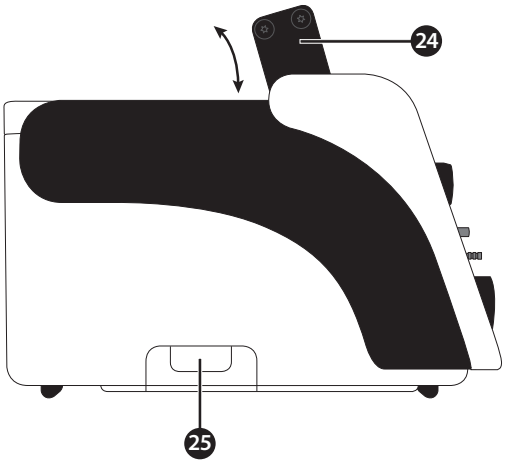
Color	Status (light)	Status
Green	Glows steadily	Mains operation
Yellow	Glows steadily	Unacknowledged power failure
White	Flashes	Device shuts down
None	Off	Confirmed AC power failure or no mains voltage/battery power

23 Battery LED

The battery LED provides information about the state of the internal battery charge.

Color	Status (light)	Battery charge state
Green	Glows steadily	≥ 60 %
Yellow	Glows steadily	≥ 20 % ... < 60 %
Red	Glows steadily	≥ 0 % ... < 20 %
White	Flashes	Device shuts down

2.5 MOVABLE AND REMOVABLE HOUSING PARTS



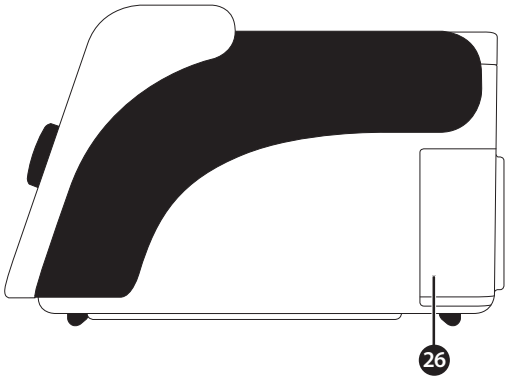


Figure 5: Left device side
Figure 6: Right side of the device with filter cassette

24 Handle (pull-out)

The handle may be pulled out for device transport.

25 Bottom flap

Valve membrane (expiration) is located under the bottom flap, which must be replaced before every change of patient or maintenance work.

26 Filter cassette

The filter cassette contains the two air filters (coarse and fine filter).

2.6 EXPLANATION OF THE TOOLBAR ICONS

Symbol	Meaning
	Clinic mode Active
	Home mode Active
	Alarm active Red icon → high-priority alarm Yellow icon → medium-priority alarm Turquoise icon → low-priority alarm
	Audio alarm paused The audible alarm has been paused for 2 min. The audible alarm of even a new alarm event will also be paused for 2 min. The audible alarm may be deactivated by pressing the alarm key before an alarm event occurs. Pressing the key again reactivates the audible alarm in case an alarm event has occurred.
	Counter for audio alarm paused Indicates how much longer the audible alarm will be paused.
	Keypad lock activated The functions of all controls are disabled, except for the ON/OFF and alarm key.
	A FiO_2 sensor is connected and "FiO_2-Monitoring" setting has been set to "Internal" in the system screen.
	The "FiO_2-Monitoring" setting has been set to "External" in the system screen. Measurement of oxygen concentration is performed using an external FiO_2-Monitoring unit.
	A FiO_2 sensor is connected, the "FiO_2-Monitoring" setting has been set to "Internal" in the system screen and oxygen is supplied.
	The "FiO_2-Monitoring" setting has been set to "External" in the system screen. Measurement of oxygen concentration is performed using an external FiO_2-Monitoring unit and oxygen is supplied.
	Spontaneous breathing detected The device has detected spontaneous breathing by the patient. This triggered the inspiration trigger. The icon will remain visible during inspiration and will shut off with the beginning of the expiration.
	Trigger lock "On"
	Trigger lock momentarily active
	SD card is inserted into the device
	No SD card inserted into the device
	SpO_2 sensor connected

Symbol	Meaning
	PC is connected via the USB port
	Error detected Selecting this symbol results in a list of all current errors (see "6.1 Error list" on page 71).
	Internal battery fully charged
	Internal battery being charged (1 bar ≙ 20 % charged)

2.7 DEVICE CONFIGURATION: MECHANICAL SUB-ASSEMBLIES

2.7.1 OVERVIEW: COMPLETE UNIT

The CARAT I pro and CARAT II pro ventilators consist of the following components:

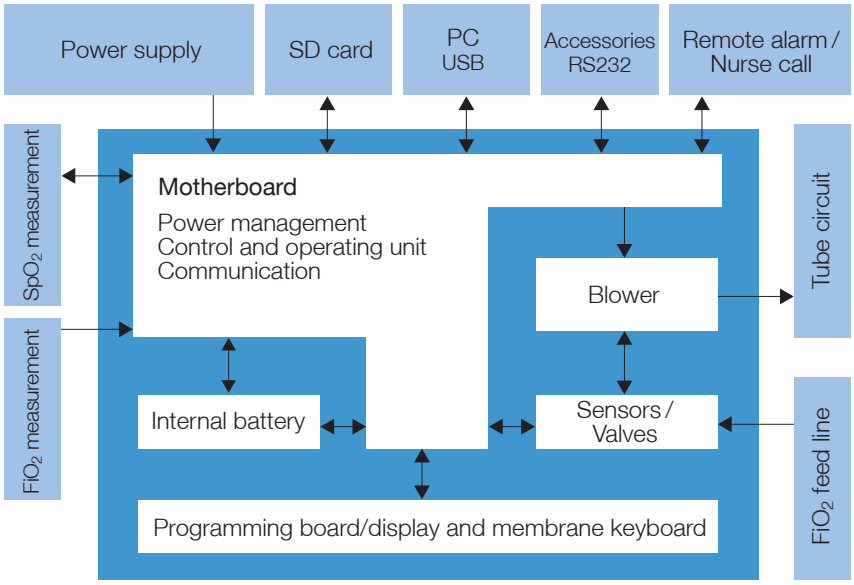


Figure 7: Block diagram for the device

2.7.2 OVERVIEW: CARAT I pro PNEUMATIC BLOCK

The pneumatic block is the connector unit for the single line patient circuit and consists of the following components:

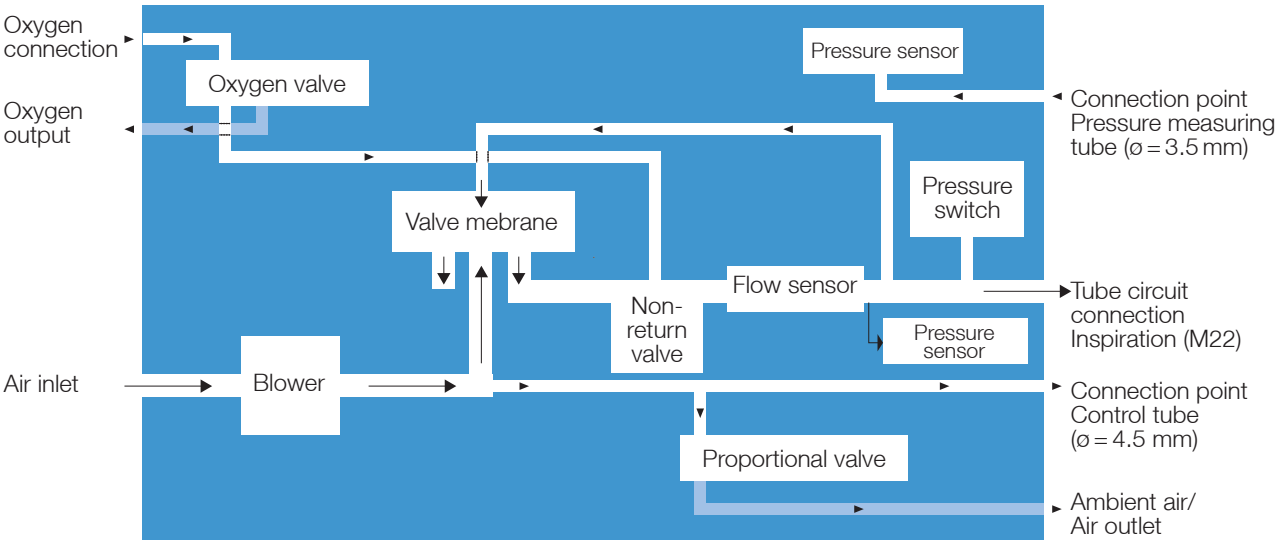


Figure 8: Pneumatic block diagram for the CARAT I pro

2.7.3 OVERVIEW: CARAT II pro PNEUMATIC BLOCK

The pneumatic block is the connector unit for the double or single line patient circuit and consists of the following components:

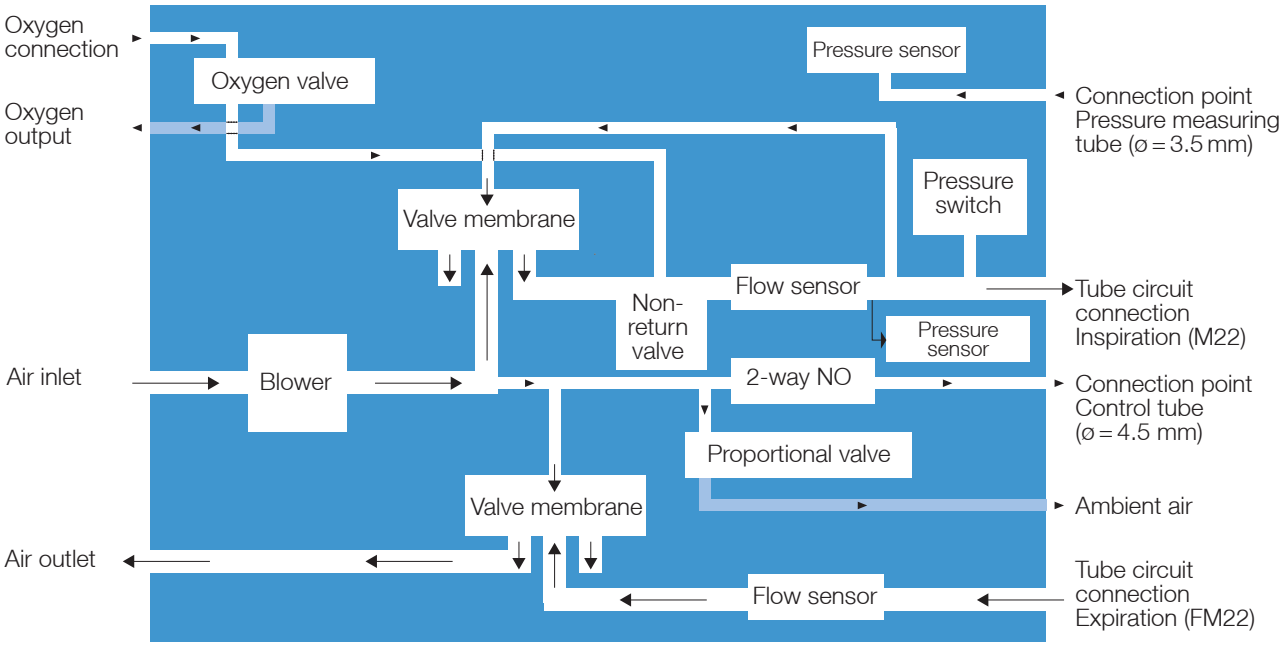


Figure 9: Pneumatic block diagram for the CARAT II pro

2.7.4 HOUSING TOP FOR CARAT I pro

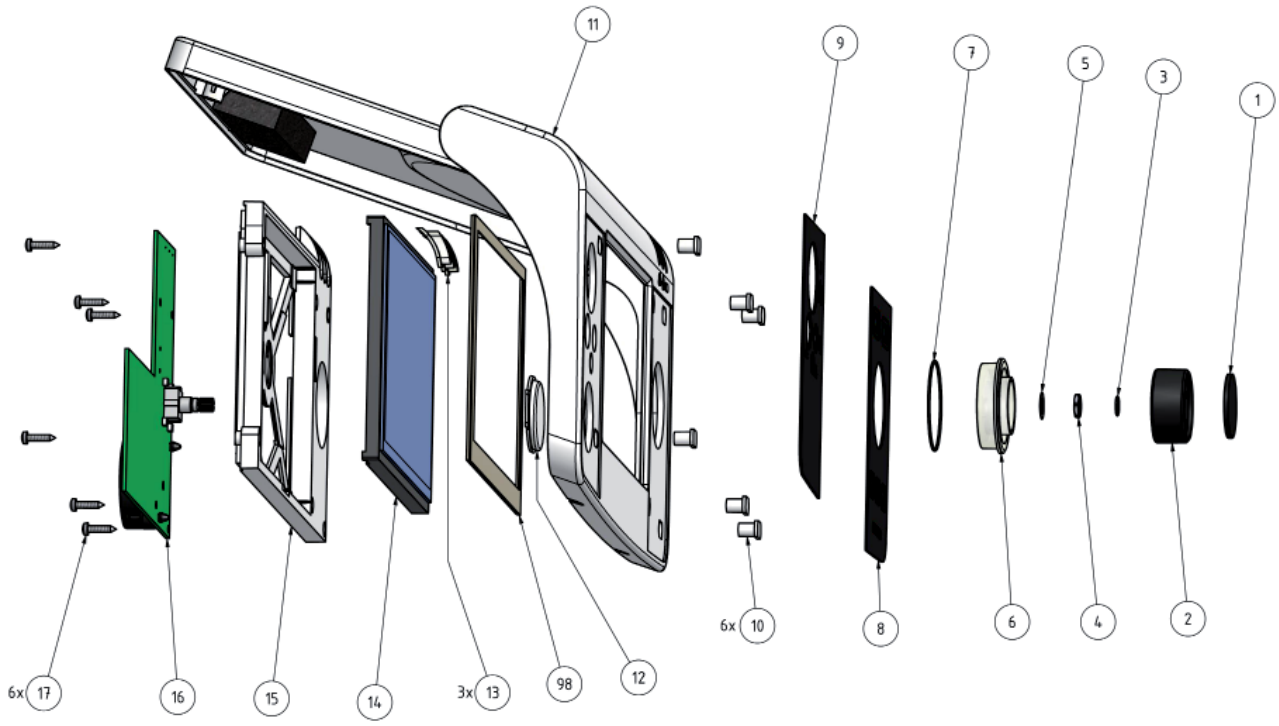


Figure 10: Housing top for CARAT I pro

1 Rotary control cover
2 Rotary control knob
3 Round wire circlip
4 M4 hex nut
5 ∅7.3 rotary control knob washer
6 Intake rotary control knob
7 39x1 O-ring
8 Membrane keyboard
9 Single line patient circuit foil
10 Threaded bush
11 Top cover
12 Blanking plug for single line
13 LED cover arch
14 Display
15 Display bezel
16 Operating circuit board
17 ST2.9x13 screw
98 Display seal

2.7.5 HOUSING TOP FOR CARAT II pro

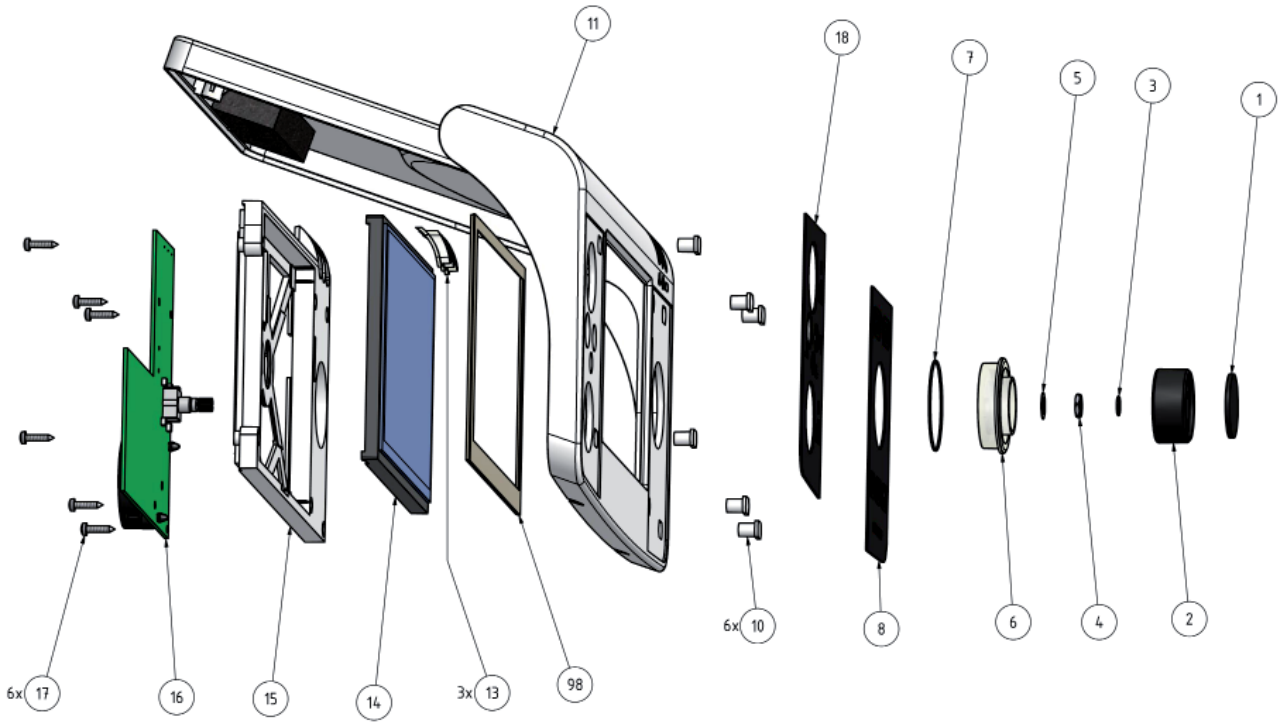


Figure 11: Housing top for CARAT II pro

1 Rotary control cover
2 Rotary control knob
3 Round wire circlip
4 M4 hex nut
5 ∅7.3 rotary control knob washer
6 Intake rotary control knob
7 39x1 O-ring
8 Membrane keyboard
10 Threaded bush
11 Top cover
13 LED cover arch
14 Display
15 Display bezel
16 Operating circuit board
17 ST2.9x13 screw
18 Double line patient circuit foil
98 Display seal

2.7.6 HOUSING BASE

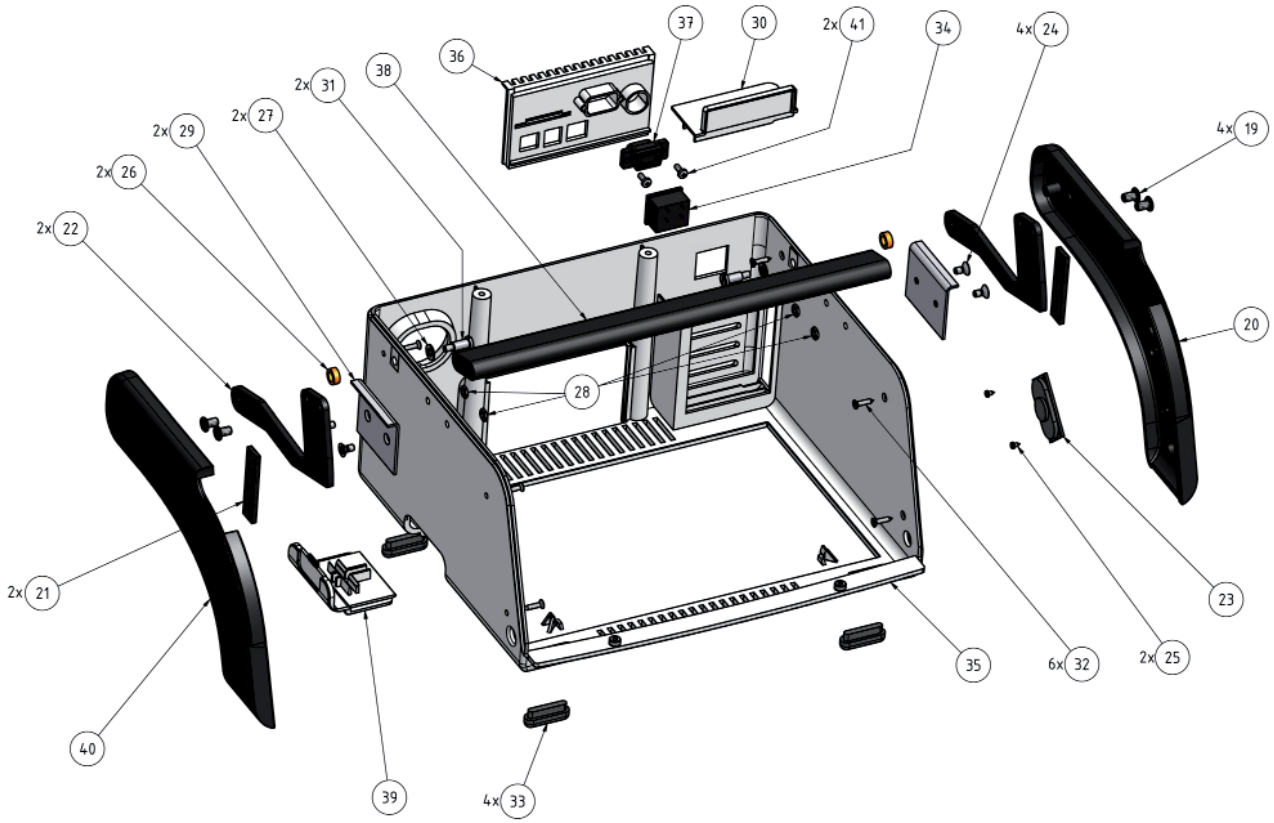


Figure 12: Housing base

19 M5x8 Torx pan head screw
20 Right trim handle
21 Felt strips
22 Lever handle
23 Speaker
24 M4x8 countersunk screw
25 Fillister head screws ST2.2x4.5
26 Spacer bush
27 ∅6.4 washer
28 M4 hex nut
29 Stop bracket
30 Filter cassette cover
31 M4x10 shoulder screw
32 ST2.9x13 countersunk screw
33 Foot
34 AC/main switch
35 Housing base
36 Interface plate
37 Sub-D9 bushing
38 Handle
39 Bottom flap
40 Left trim handle
41 M3x8 pan head screw

2.7.7 INTERNAL FRAME

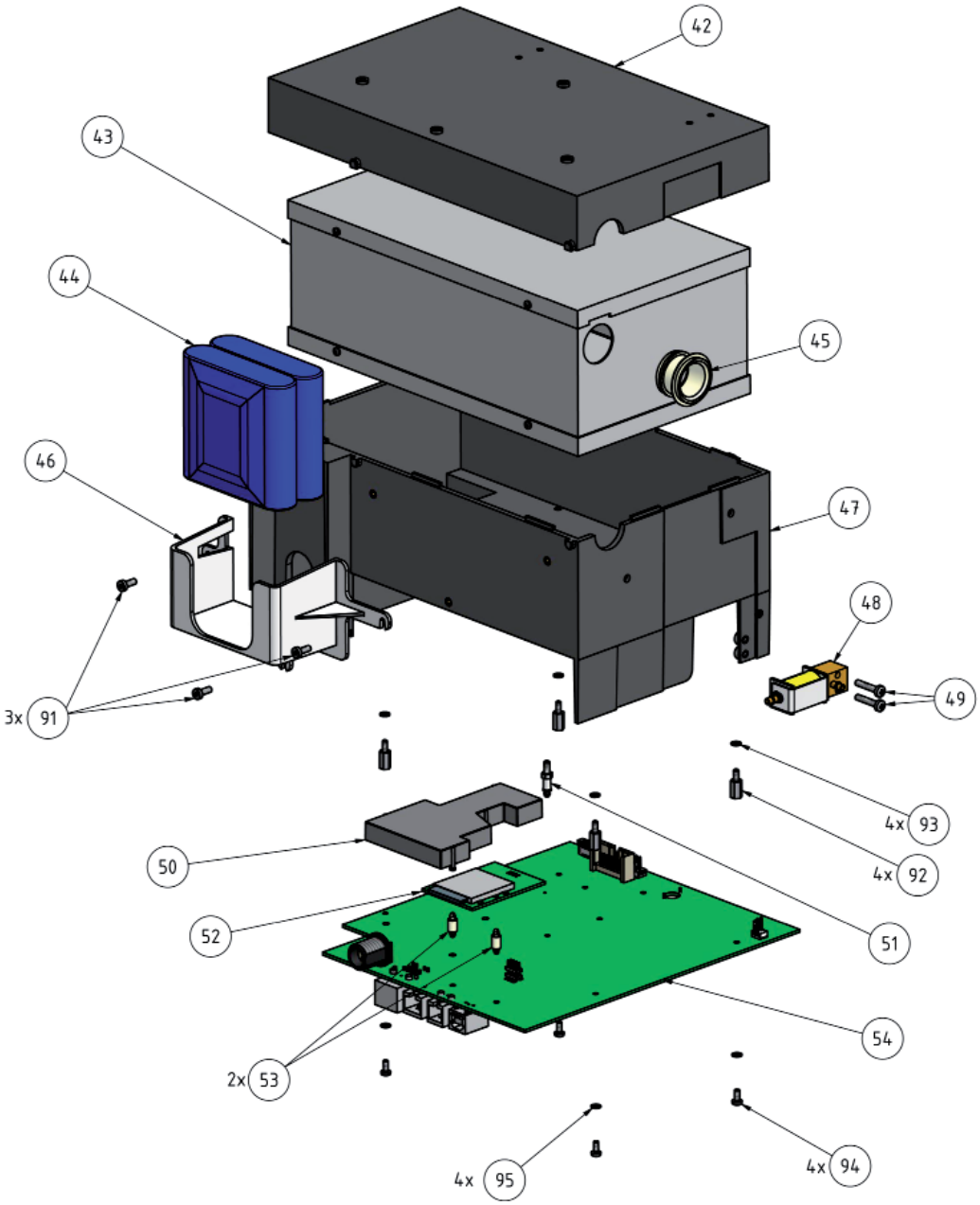


Figure 13: Internal frame

42 Internal frame for top
43 Blower box
44 Battery pack (Li-Ion)
45 Seal for air outlet CARAT (box)
46 Battery holder
47 Internal frame for Base
48 Control tube valve for CARAT II pro
49 M3x16 pan head screw
50 Fire protection cover
51 LP-spacer MSCBT-M3-6
52 LP SD card module
53 LP-spacer ∅2.5x6.4
54 Control circuit board
91 Allen screw®
92 M2.5x9.0 spacer bolts
93 ∅2.7 steel washer
94 M2.5x6 pan head screw
95 ∅2.7 plastic washer

2.7.8 SENSOR BLOCK FOR CARAT I pro

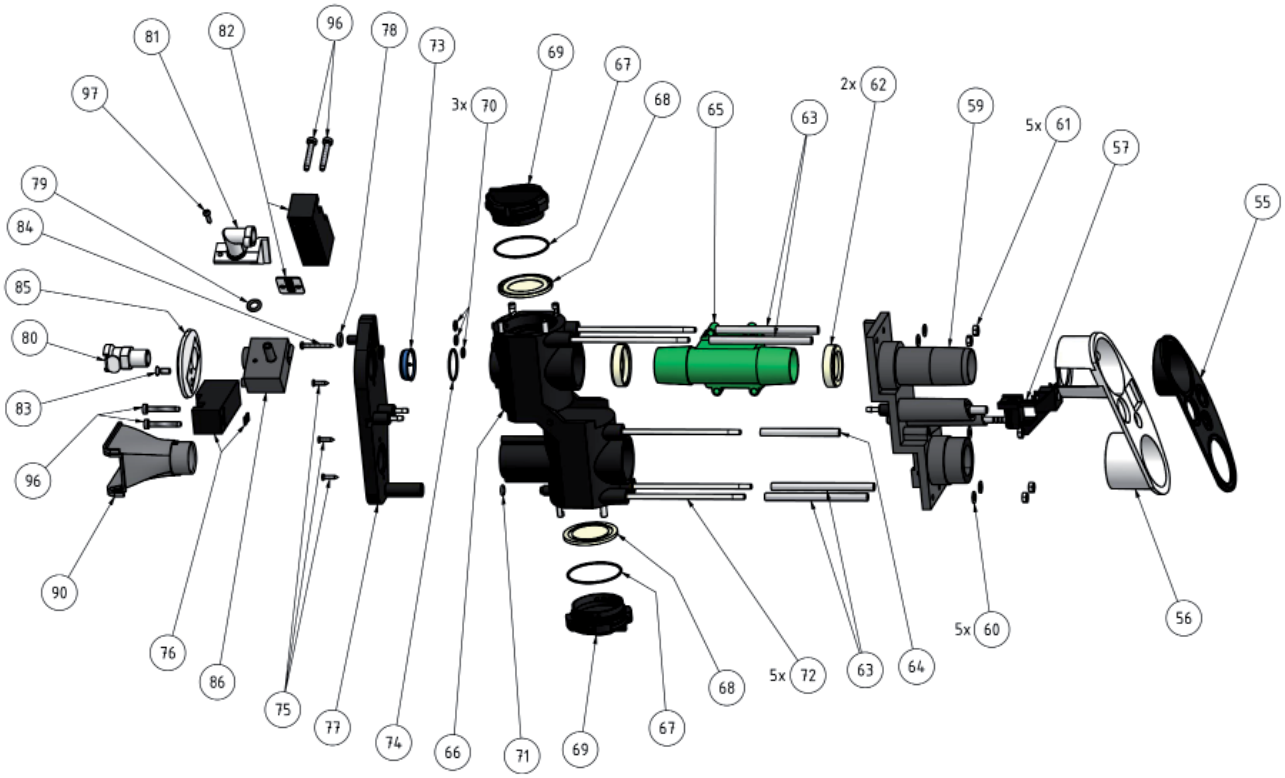


Figure 14: Sensor block for CARAT I pro

55 Seal for tube connections
56 Support frame for tube connection (seal)
57 O_2 sensor bushing
59 CARAT I pro tube connector
60 ∅ 3.2 washer
61 M3 hex nut
62 Flow sensor seal
63 Long spacer sleeve
64 Short spacer sleeve
65 Flow sensor
66 Sensor block (without 65, 67, 68, 69, 72, 77)
67 30x1.2 O-ring
68 Valve membrane
69 Valve cover
70 4x1 O-ring
71 3.8x1.25 O-ring
72 M3 tie rod
73 Non-return valve
74 17x1 O-ring
75 ST2.2x9.5 countersunk screw
76 Proportional valve with seal and bushing strip
77 Valve base
78 4.6x1.85 O-ring
79 5x1.8 O-ring
80 FiO_2 coupling
81 Oxygen adapter (internal)
82 Oxygen valve (3/2-way valve) with seal and bushing strip
83 M3x8 countersunk screw
84 ST2.2x19 fillister head screw
85 Baffle O_2 adapter
86 Oxygen block
90 Air outlet
96 3.0x20 self-tapping screw
97 ST2.2x9.5 fillister head screw

2.7.9 SENSOR BLOCK FOR CARAT II pro

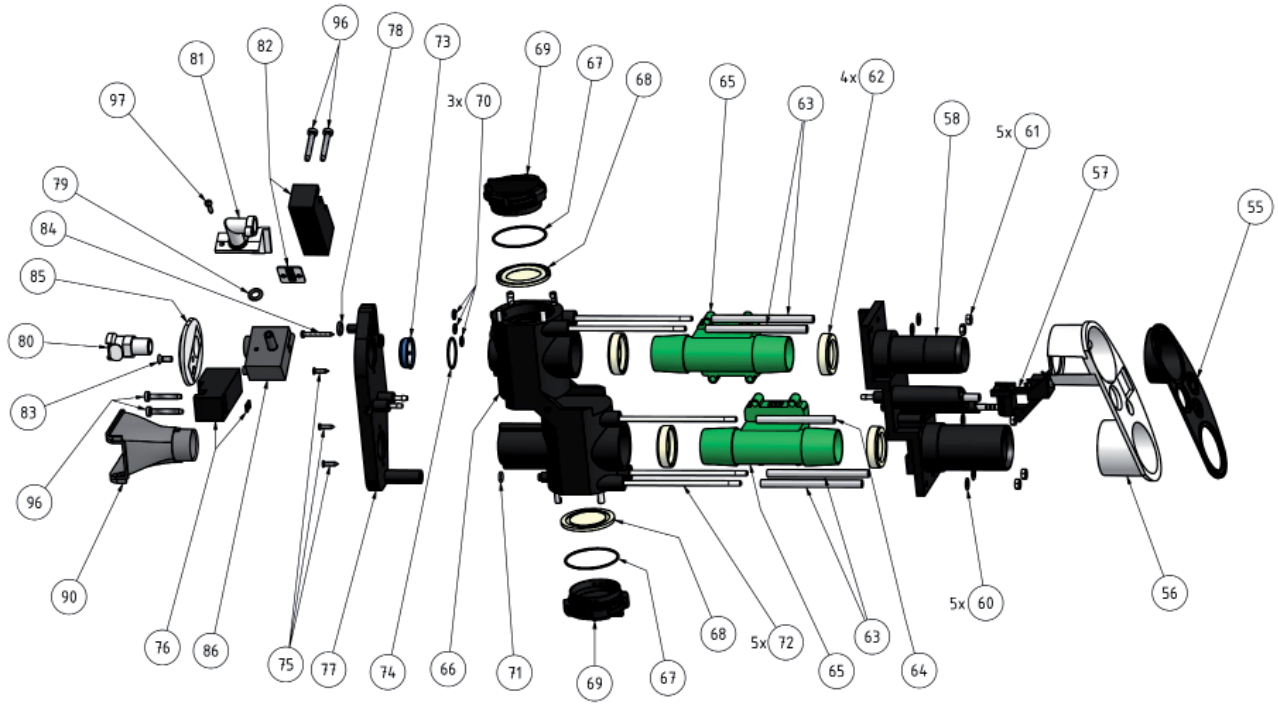


Figure 15: Sensor block for CARAT II pro

55 Seal for tube connections
56 Support frame for tube connection (seal)
57 O_2 sensor bushing
58 CARAT II pro tube connector
60 ∅ 3.2 washer
61 M3 hex nut
62 Flow sensor seal
63 Long spacer sleeve
64 Short spacer sleeve
65 Flow sensor
66 Sensor block (without 65, 67, 68, 69, 72, 77)
67 O-Ring 30x1.2
68 Valve membrane
69 Valve cover
70 4x1 O-ring
71 3.8x1.25 O-ring
72 M3 tie rod
73 Non-return valve
74 17x1 O-ring
75 ST2.2x9.5 countersunk screw
76 Proportional valve with seal and bushing strip
77 Valve base
78 4.6x1.85 O-ring
79 5x1.8 O-ring
80 FiO_2 coupling
81 Oxygen adapter (internal)
82 Oxygen valve (3/2-way valve) with seal and bushing strip
83 M3x8 countersunk screw
84 ST2.2x19 fillister head screw
85 Baffle FiO_2 adapter
86 Oxygen block
90 Air outlet
96 3.0x20 self-tapping screw
97 ST2.2x9.5 fillister head screw

2.7.10 COMPLETE DEVICE ASSEMBLY

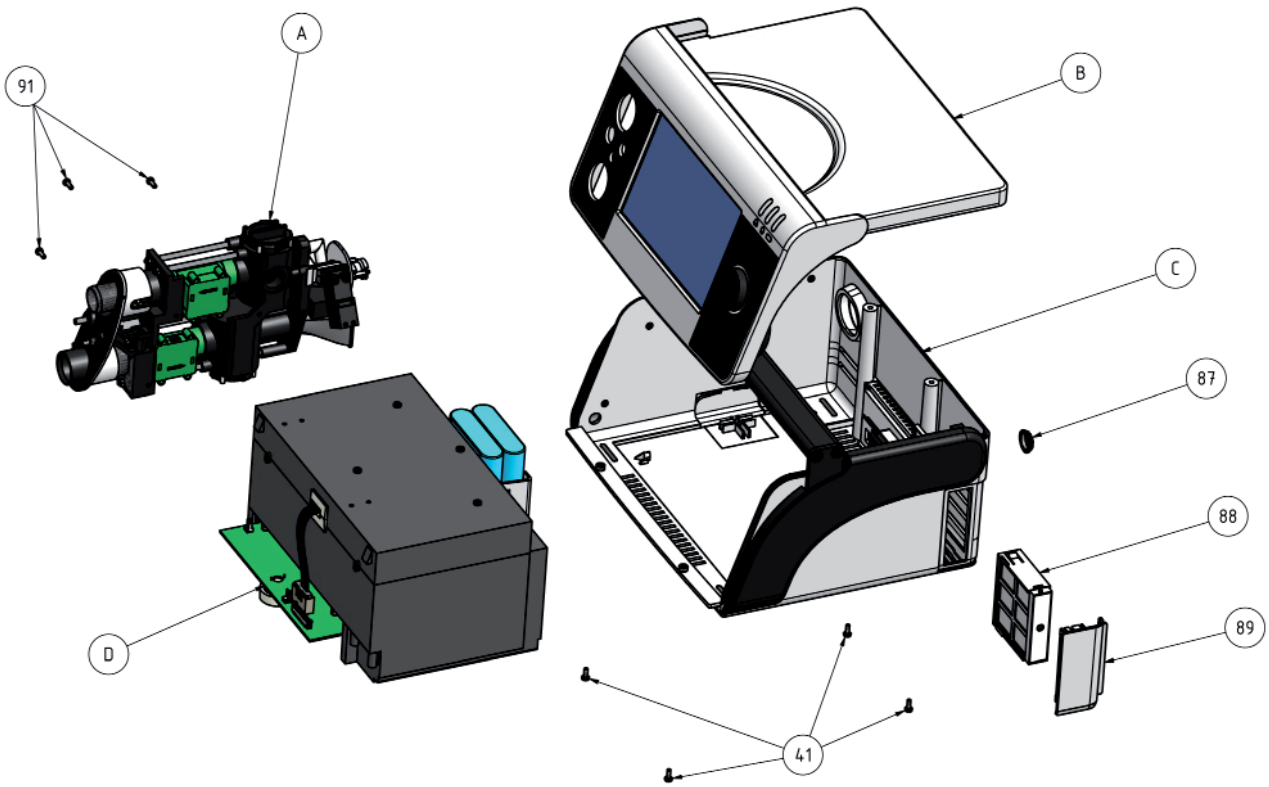


Figure 16: Complete device assembly

41 M3x8 pan head screw
87 DC connection point front nut
88 Filter cassette
89 Filter cassette cover
91 M3x8 Allen® screw
A CARAT II pro sensor block, complete with flow sensor
B CARAT II top cover
C Housing base
D Complete internal frame

2.7.11 CARAT I pro TUBE CONNECTION DIAGRAM

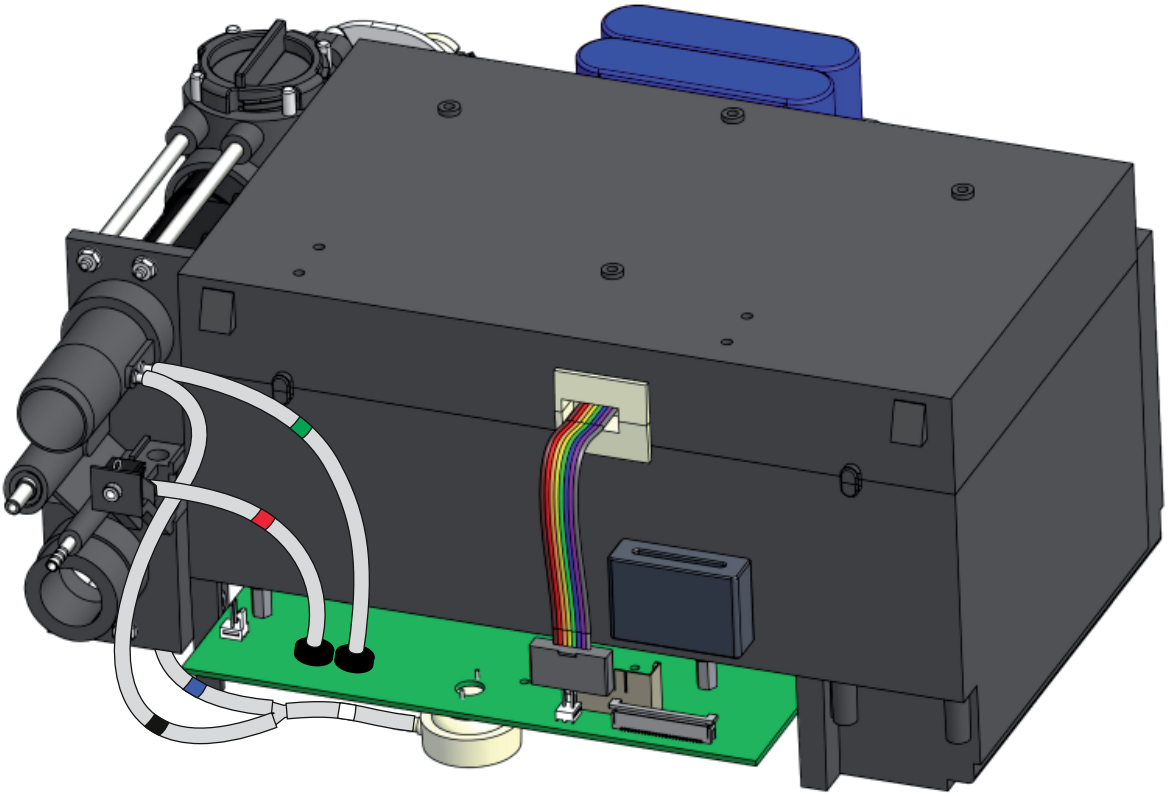


Figure 17: Tube connection diagram for CARAT I pro, part 1

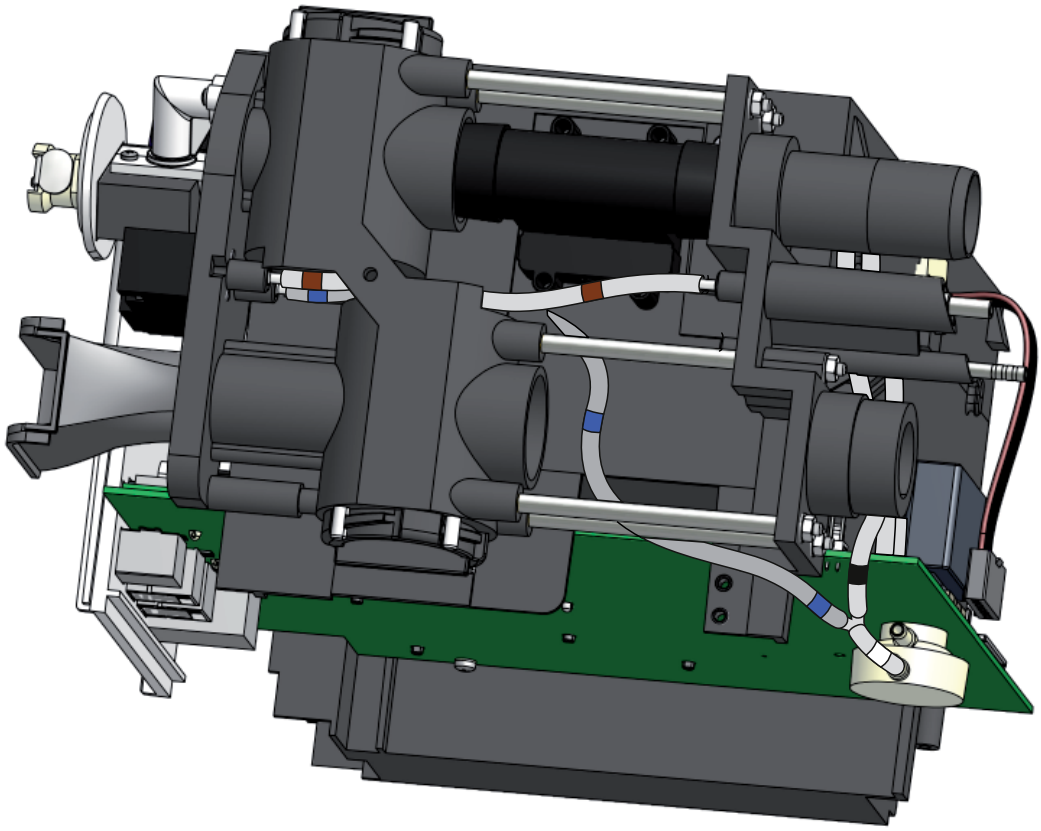


Figure 18: Tube connection diagram for CARAT I pro, part 2

2.7.12 CARAT II pro TUBE CONNECTION DIAGRAM

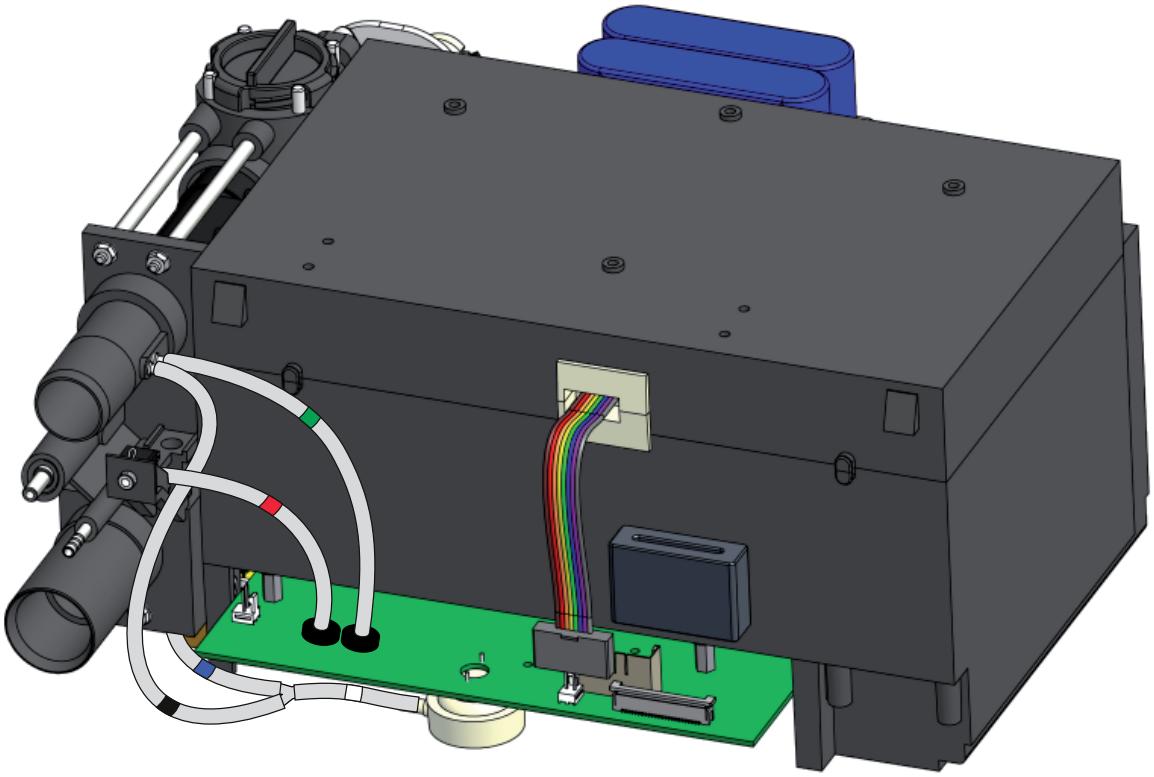


Figure 19: Tube connection diagram for CARAT II pro, part 1

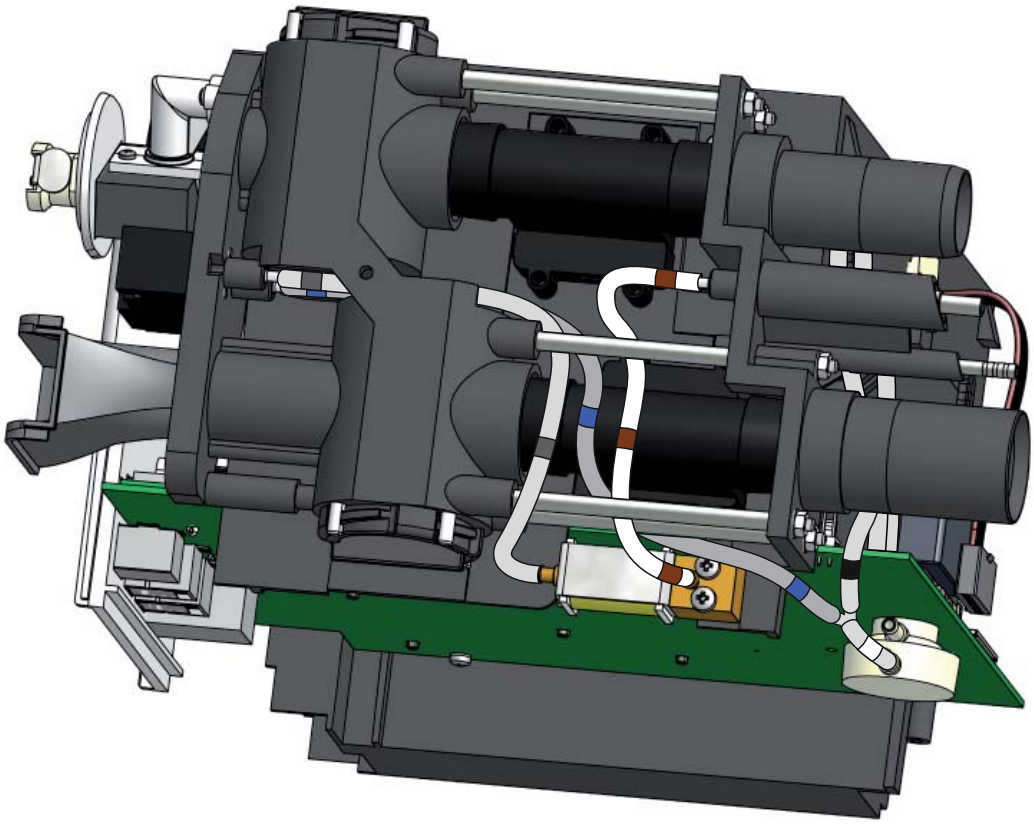


Figure 20: Tube connection diagram for CARAT II pro, part 2

2.8 DEVICE CONFIGURATION: ELECTRONIC COMPONENTS

2.8.1 CONTROL CIRCUIT BOARD

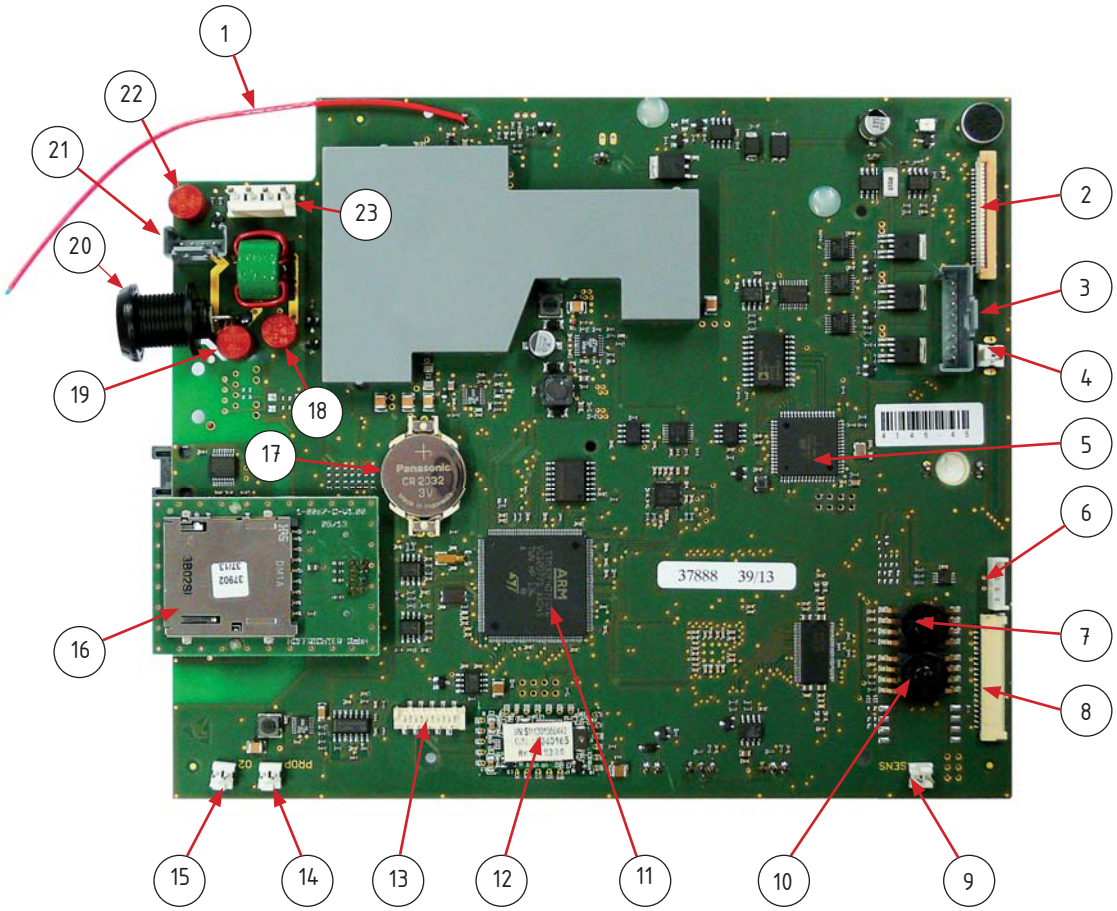


Figure 21: Control circuit board top

1 NTC
2 Cable connection point for operating circuit board
3 Cable connection point for motor
4 Cable connection point for speaker
5 ATmega 1281 steering controller
6 Cable connection point for display backlight
7 Inspiration pressure sensor (measurement without pressure measuring tube)
8 Cable connection point for LVDS Display
9 Cable connection point for FiO_2 measuring cell
10 Pressure sensor for pressure measuring tube (mask pressure)
11 STM32 F407IGT6 operating controller
12 SpO_2 module
13 Cable connection point for SpO_2 sensor
14 Cable connection point for proportional valve
15 Cable connection point for FiO_2 valve
16 LP SD card module
17 CR2032, 3 V clock battery
18 Internal battery pack input fuse (T4A)
19 Input fuse 12 V DC (F8A)
20 DC connector bushing
21 Cable connection point for battery pack
22 Input fuse 24 V DC (F8A)
23 Cable connection point for AC/ main switch

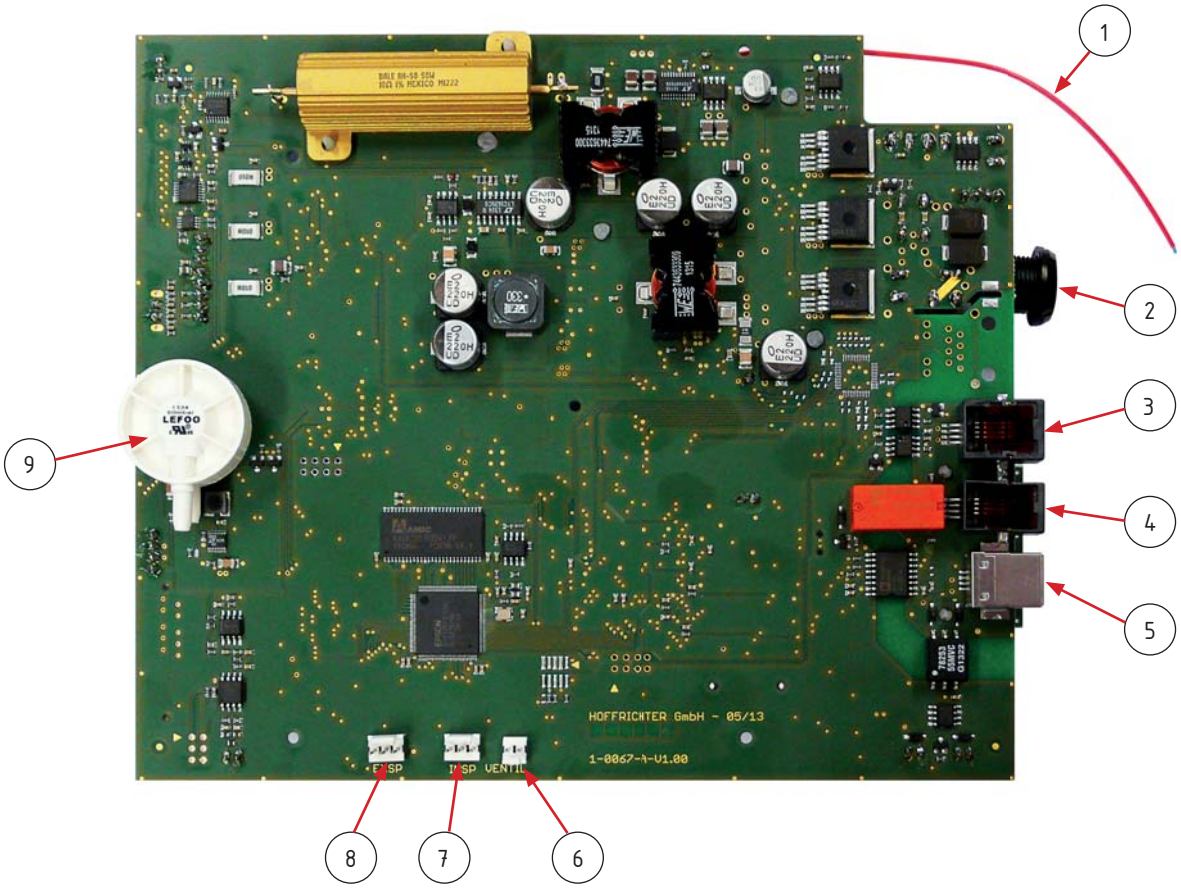


Figure 22: Control circuit board bottom

1 NTC
2 DC connector bushing
3 RS232 Interface
4 Connector bushing for remote alarm/nurse call
5 USB interface
6 Cable connection point for CARAT II pro control tube valve (2/2-way valve)
7 Cable connection point for inspiration flow sensor
8 Cable connection point for expiration flow sensor
9 60 mbar maximum pressure governor

2.8.2 OPERATING CIRCUIT BOARD

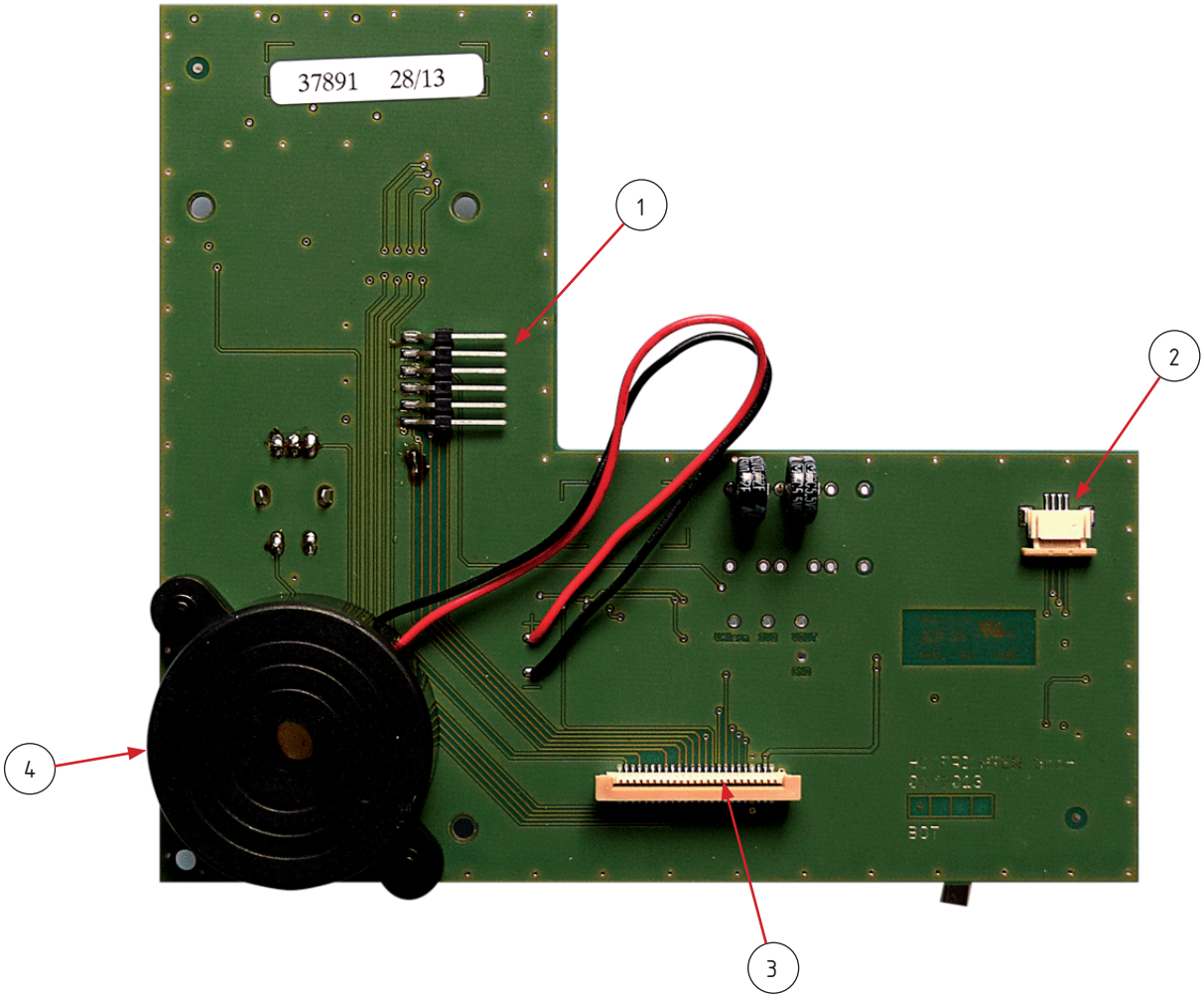


Figure 23: Operating circuit board top

1 Cable connection point for membrane keyboard
2 Cable connection point for touch display
3 Cable connection point for control circuit board
4 Piezo signal transmitter

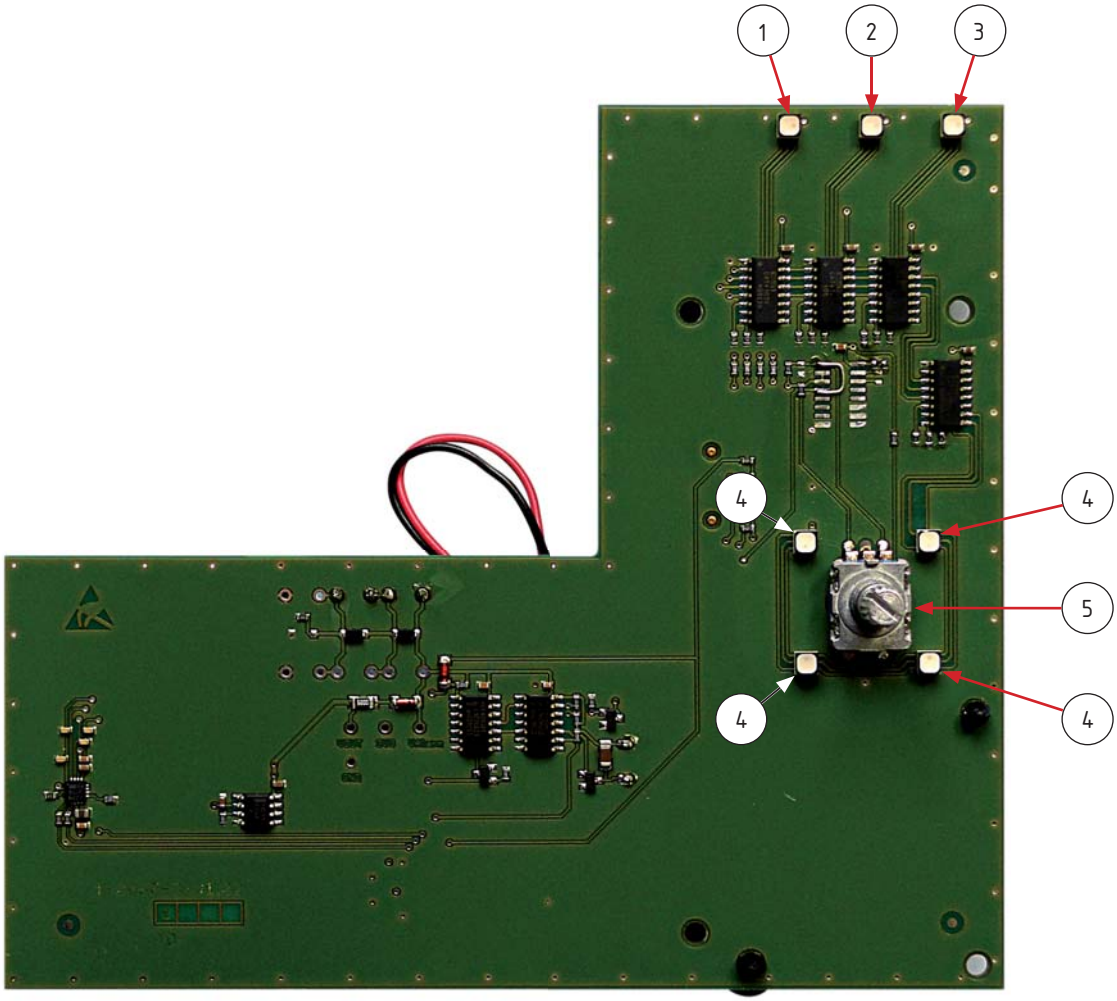


Figure 24: Operating circuit board bottom

1 Alarm LED
2 Power LED
3 Battery LED
4 MFK background LED
5 Encoder

CHAPTER 3
MAINTENANCE WORK

⚠ CAUTION
Make sure that all ventilation and alarm parameters have been restored in the device after all maintenance work has been completed.

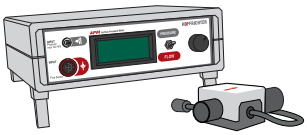
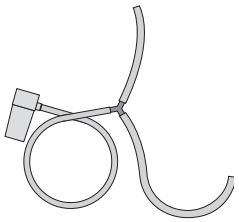
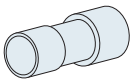
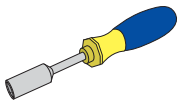
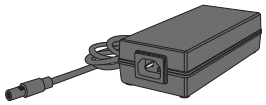
3.1 PREPARATION

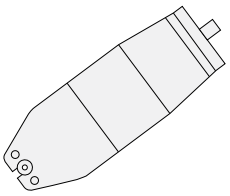
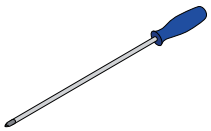
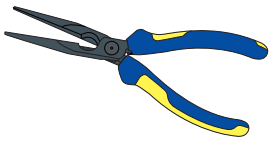
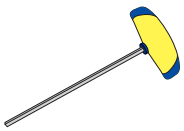
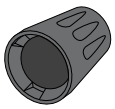
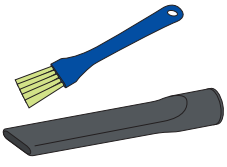
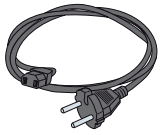
3.1.1 PROTECTING AND DISINFECTING AGENTS

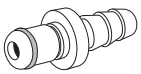
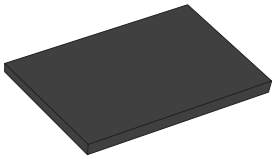
- Hand disinfectant: e.g. Sterillium® (Bode) [or local equivalent]
- Surface disinfectant: e.g. schülke wipes [or local equivalent]
- In case of dangerously contaminated medical products (MRSA), additional personal protective gear must be used, like disposable gloves, masks and aprons.

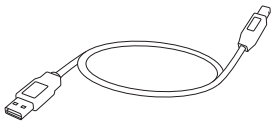
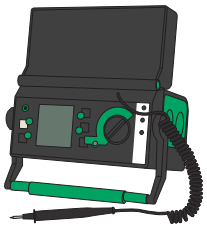
3.1.2 TOOLS AND MEASURING EQUIPMENT

The following tools and measuring equipment are needed for the maintenance work:

Name Article number	Figure
Pressure/Flow meter with the following specifications: • Pressure/Flow measuring range: 0...100 hPa (± 0.2 % from the pressure measuring range) 0...200 l/min (± 0.2 % from the flow measuring range) • Display accuracy: Pressure: 0.01 hPa Flow: 0.1 l/min • Units: hPa, mbar, cmH_2O, l/min e.g. APM by HOFFRICHTER 00004040	
Scope of delivery APM including:	
APM incl. flow sensor 00004832	
APM blind plug 00004831	
Therapy tube with pressure measuring tube 00007116	
Adapter bacterial filter 00004933	
SW10 socket wrench	
Canned air or fixed compressed air connection	
Switched-mode power supply 00014206	

Name Article number	Figure
Test lung with the following specifications: • Compliance (hardness of the lungs): 25 ml/mbar • Vt = 500 ml, PEEP = 0 mbar • Resistance (airway resistance): 20 mbar/l/s • Tidal volume: max. 1000 ml 00004960	
Phillips head screwdriver (PH1 x 200)	
Needle nose pliers	
Wire cutters	
Allen wrench SW 2.5	
M14x1 socket wrench 00004130	
Soft brush and vacuum cleaner	
Power cable 31100023	

Name Article number	Figure
PC with the following minimum system requirements: • MS-Windows® 98, 2000, NT4.0, ME, XP, Server 2003, Vista, 7 or 8 • Microsoft .NET Framework 2.0 Redistributable (x86) • one free COM interface per device	
Straight FiO_2 connection adapter 41000104	
Softpad	
User's manual for CARAT I pro for physicians and medical professionals 50000611	
Service manual 50000650	

Name Article number	Figure
USB cable (PC cable) 00005291	
PC software "EASYset"	
Device for checking electrical safety (e.g. SECUTEST SIII/ DIN EN 62353:2008)	
User's manual for CARAT II pro for physicians and medical professionals 50000625	
Hygiene Concept 50000652	

⚠CAUTION

All tools, measuring equipment and aids possibly exposed to contamination must be cleaned after they have been used and treated with disinfectant.

3.1.3 UNPACKING AND DISINFECTING

⚠ CAUTION
To protect against germs, the surface of the device and, where present, the humidifier must be treated with a disinfectant immediately after unpacking.

3.1.4 CHECKING FOR EXTERNAL DAMAGE

Before starting the service works, check the device for external damage.

3.1.5 DATA BACKUP

We recommend that a backup is carried out before starting maintenance work. Connect the device to a PC and use the PC software "EASYset" (not yet available) to read out and save the device data.

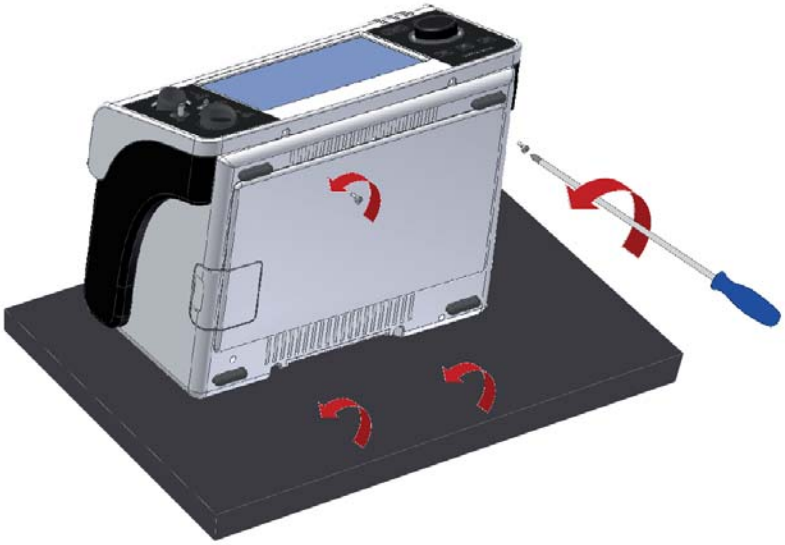
3.2 DISASSEMBLE THE DEVICE

3.2.1 REMOVE TOP COVER

Required tools/auxiliary material:
Phillips head screwdriver PH1 x 200, socket wrench M14x1, softpad

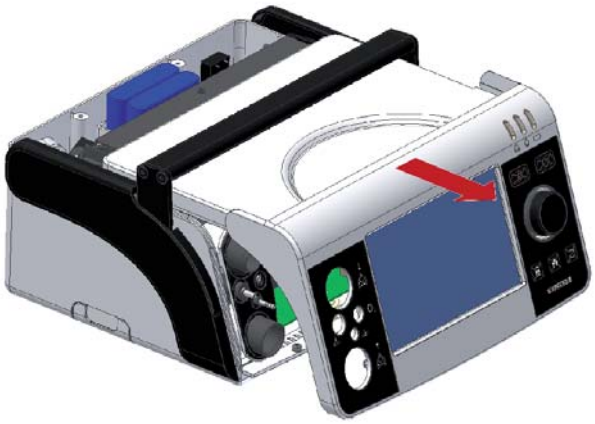
1. Switch off the device at the main switch.
2. Disconnect the device from the power supply.
3. Disconnect the attached accessories from the device (tube circuit, FiO_2 sensor, etc.)
4. If necessary, remove the HOFFRICHTER warranty seal.
5. Pull the filter cassette from the device.
6. Use the socket wrench to loosen the front nut of the DC connection.

7. Place the back of the device on a softpad.
8. Use the screwdriver to loosen the four housing retaining screws.

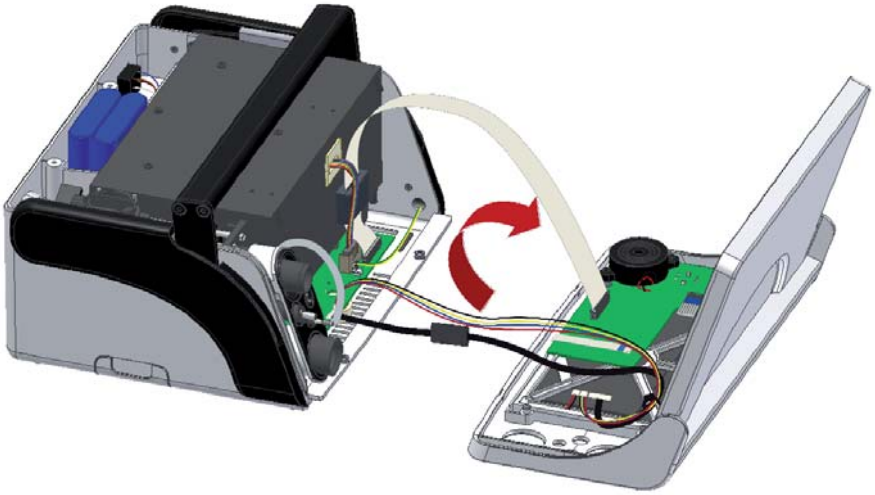


9. Replace the device back on its housing base.

10. Lift the handle and pull off the top cover towards the front.



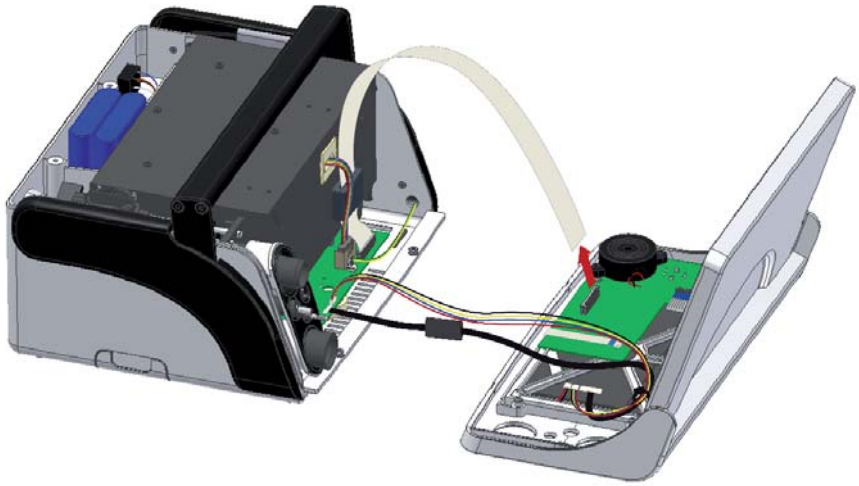
11. Lay the top cover with the display side face down in front of the device.



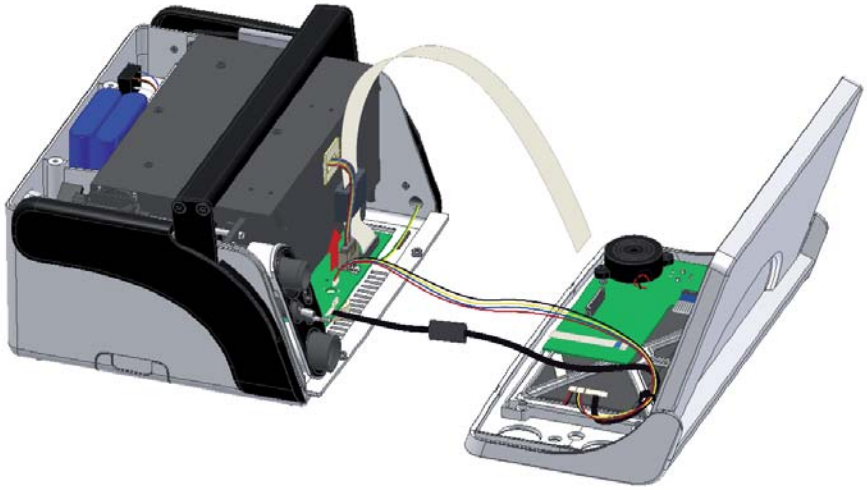
3.2.2 DISCONNECT THE TOP COVER FROM THE DEVICE

Required tools/auxiliary material: none

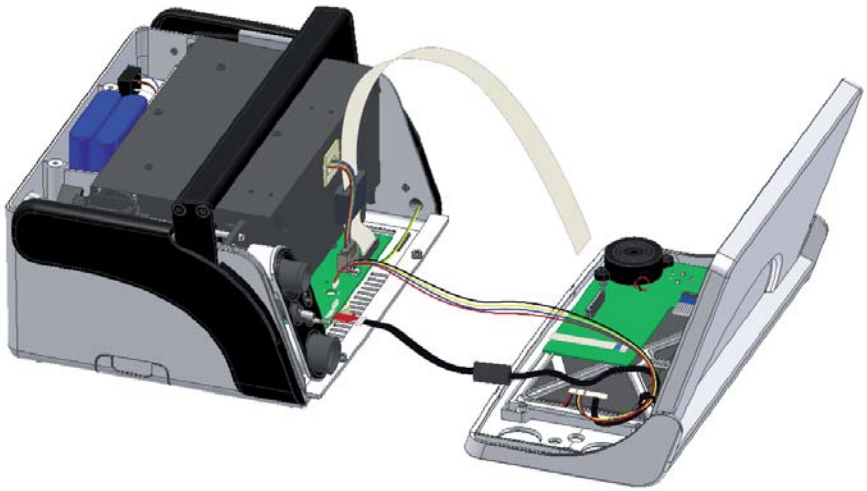
1. Detach the "Operating circuit board" ribbon cable from the device's operating circuit board.



2. Detach the "Display backlighting" (quadripolar) from the control circuit board.



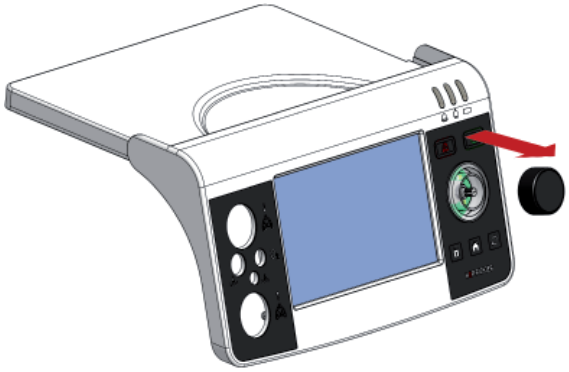
3. Detach the "Display“ cable from the control circuit board.



3.2.3 REMOVE THE MULTIFUNCTION KEY AND OPERATING CIRCUIT BOARD

Required tools/auxiliary material: SW10 socket wrench, Phillips head screwdriver PH1

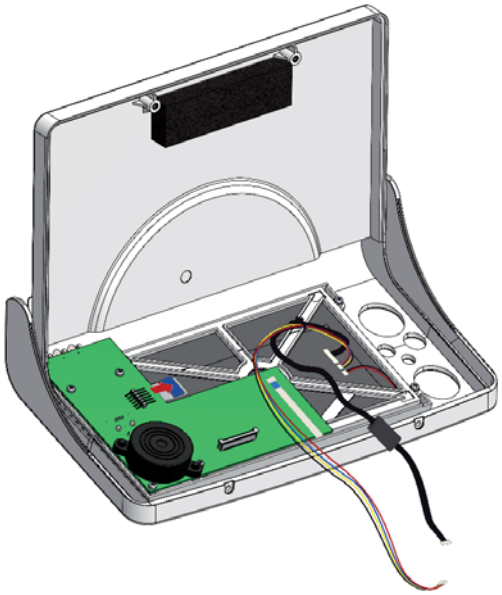
1. Pull firmly at the MFK to pull if off.



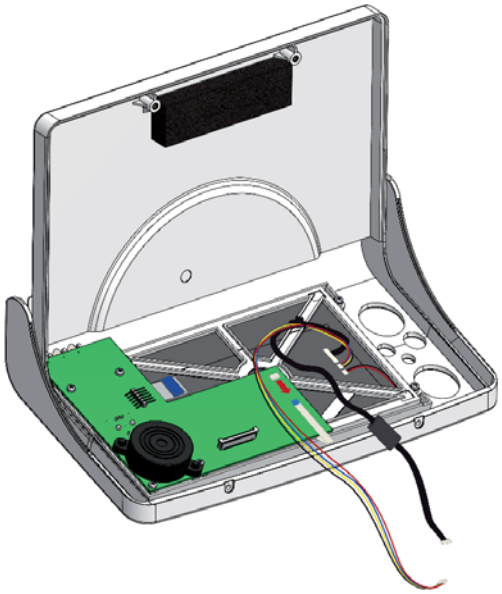
2. Unscrew the nut using the socket wrench and remove the washer.

3. Turn over the top cover.

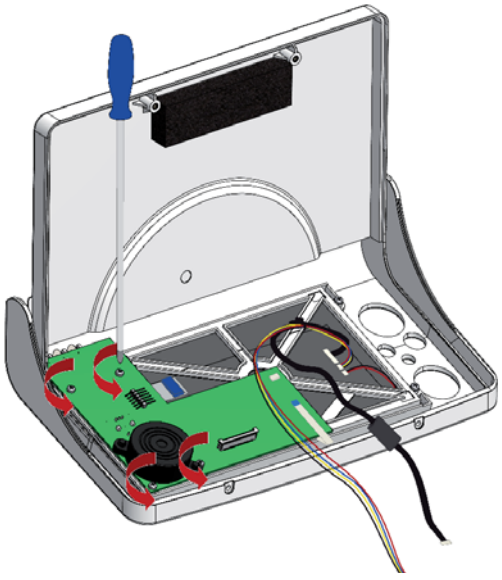
4. Detach the "Membrane keyboard" ribbon cable from the operating circuit board.



5. Detach the "Touch display" ribbon cable from the operating circuit board.



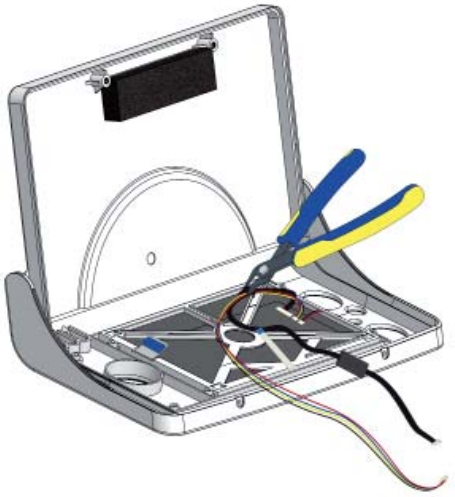
6. Loosen the 4 screws and remove the operating circuit board.



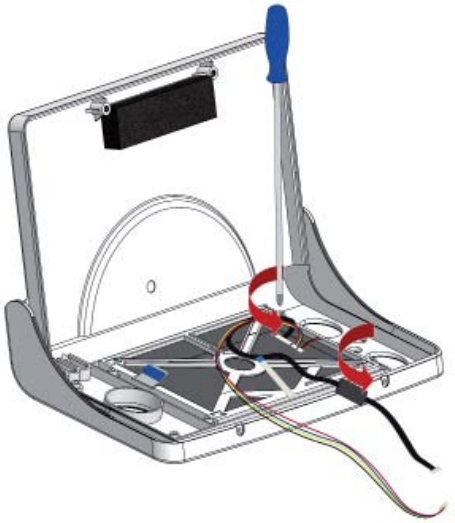
3.2.4 REMOVE THE DISPLAY FRAME AND THE DISPLAY

Required tools/auxiliary material: Wire cutters, Phillips screwdriver PH1

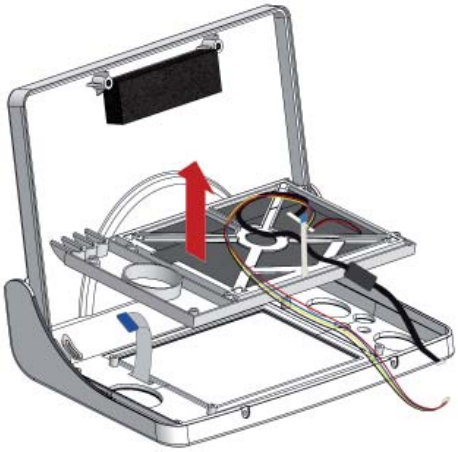
1. Disconnect the cable tie with the wire cutters.



2. Loosen the 2 screws from the display frame.



3. Remove the display frame with the display from the top cover.



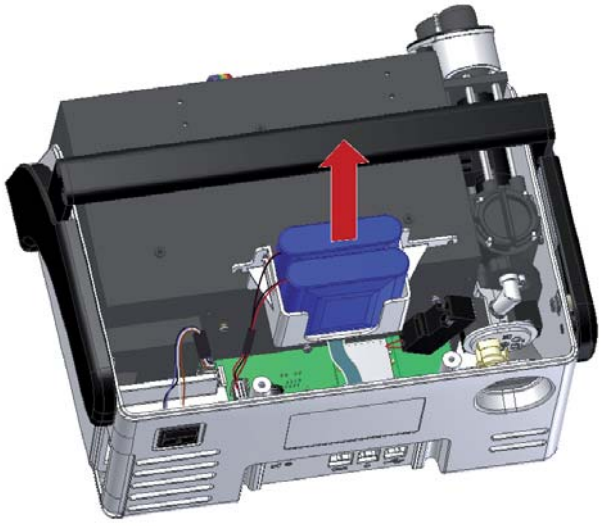
3.2.5 REMOVE INTERNAL FRAME

Required tools/auxiliary material: none

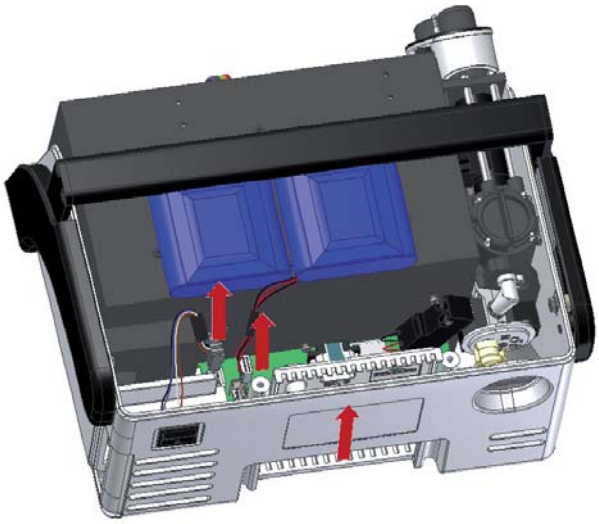
1. Detach the speaker cable from the control circuit board.

2. Slightly lift the internal frame at the front and pull it out about 5 cm.

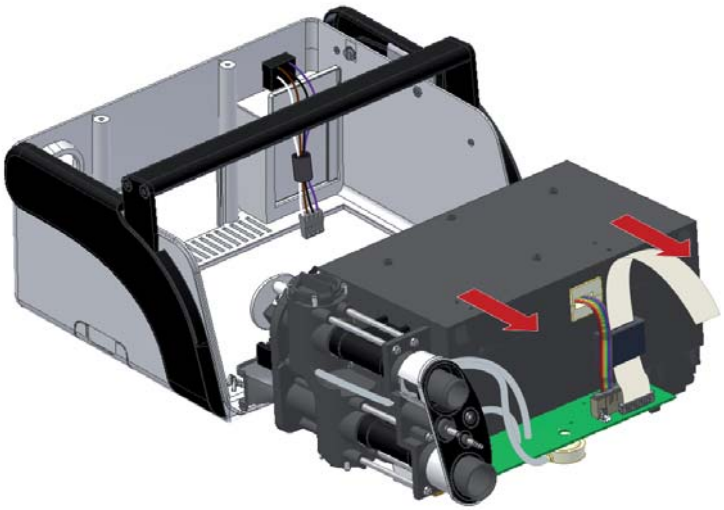
3. Pull the battery holder from the internal frame.



4. Remove the batteries from the battery holder.
5. Temporarily place the batteries on the internal frame.
6. Detach the "Battery pack" and "AC/main switch" cables from the control circuit board.
7. Pull the interface plate up and out the top.



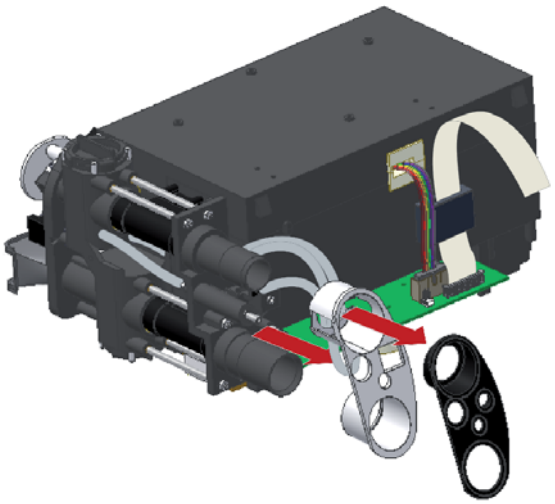
8. Pull the internal frame towards the front and out of the bottom of the housing.



3.2.6 UNINSTALL THE TUBE CONNECTION SEALS AND THE SUPPORT FRAME

Required tools/auxiliary material: none

1. Remove the support frame and the tube connection seals from the sensor block.

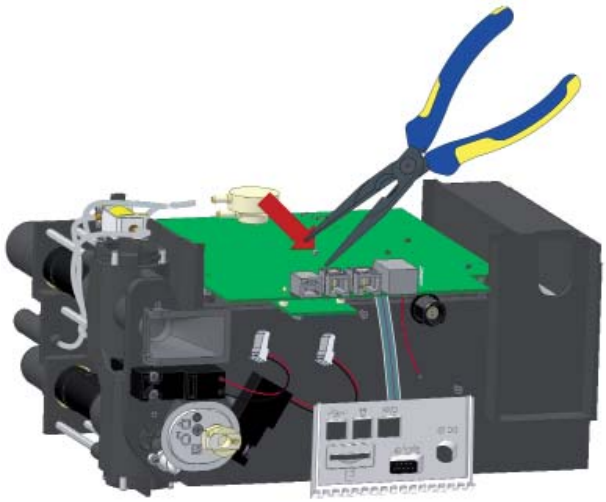


3.2.7 UNINSTALL THE CONTROL CIRCUIT BOARD

Required tools/auxiliary material: Phillips head screwdriver PH1, needle-nose pliers

1. Detach all cables and tubing from the control circuit board.
2. Loosen the 4 control circuit board screws.

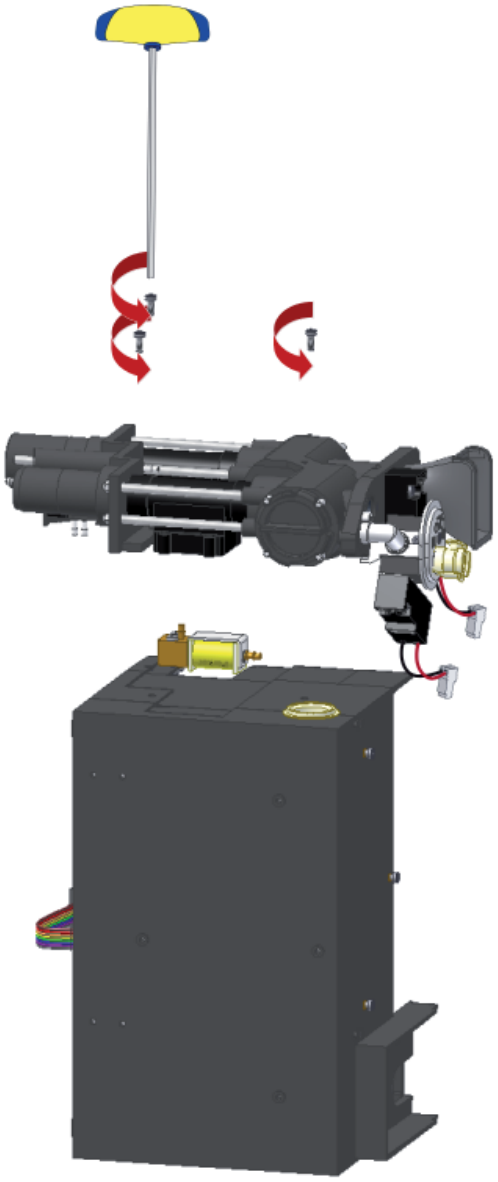
3. Depress the center of the plastic dome using needle-nosed pliers and remove the control circuit board from the internal frame.



3.2.8 UNINSTALL THE SENSOR BLOCK

Required tools/auxiliary material: Allen wrench 2.5

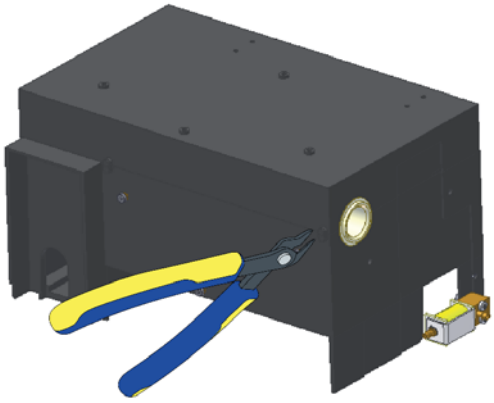
1. Disconnect all tubes from the sensor block and from the control tube membrane (only on CARAT II pro).
2. Use the Allen wrench to loosen the 3 screws from the sensor block and remove the sensor block from the internal frame.



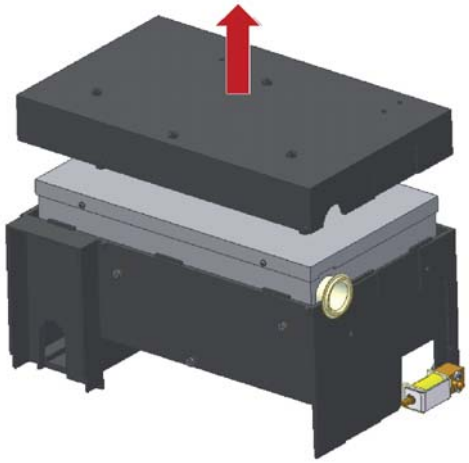
3.2.9 REMOVE THE BLOWER BOX

Required tools/auxiliary material: Wire cutters

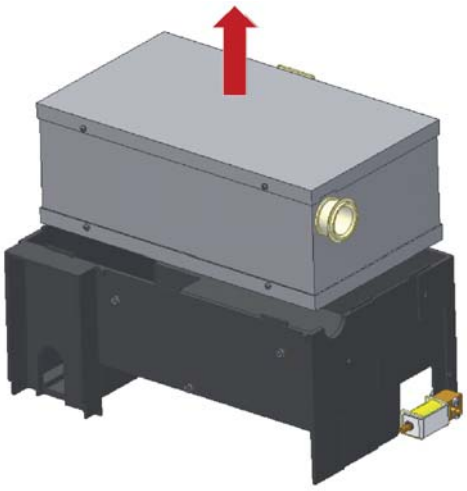
1. Use wire cutters to cut through all 4 cable ties holding the top and bottom of the internal frame together.



2. Remove the top cover

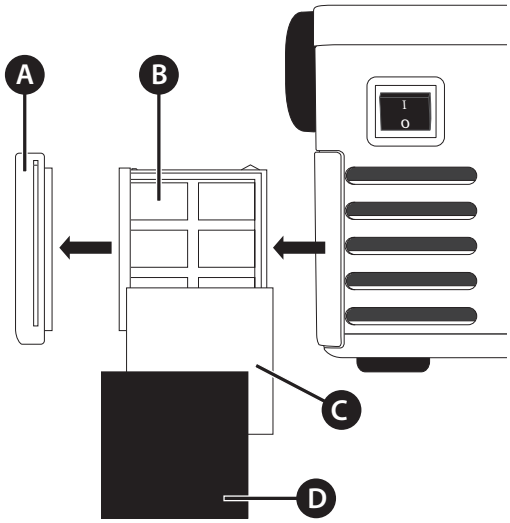


3. Lift out the blower box.



3.3 HARDWARE MAINTENANCE

3.3.1 AIR FILTER



A Filter frame cover B Filter cassette **C** Fine filter (white)
D Course filter (black)

Figure 25: Filter cassette design

3.3.2 REPLACE COURSE AND FINE FILTER

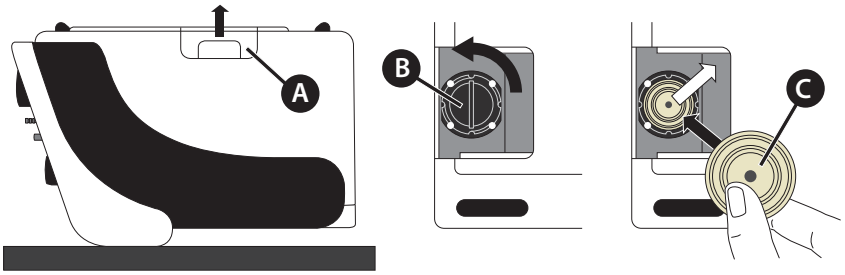
When	Replacement parts	Equipment
• Once per year (at each maintenance visit)	• Maintenance kit 1	• None

How to replace the course filter and the fine filter

1. Pull the filter cassette from the device.
2. Remove the course filter (black) and the fine filter (white).
3. Insert the new filter back into the cassette.
4. Slide the filter cassette into the device.

3.4 REPLACE (EXPIRATION) VALVE MEMBRANE

When?	Replacement parts	Equipment
• Every 6 months, if the device has been operated without bacterial filter.	• Membrane replacement kit	• Softpad



A Bottom flap **B** Valve cover **C** Valve membrane

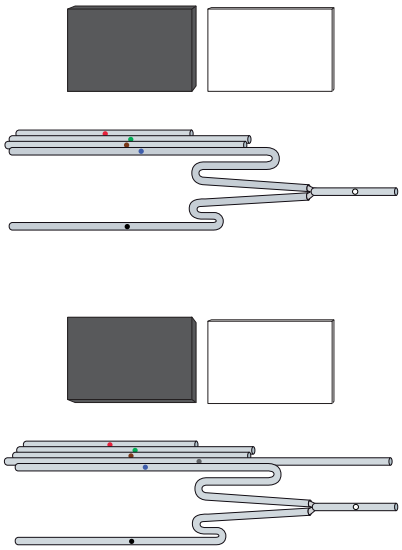
Figure 26: Replace valve membrane (expiration)

To replace the valve membrane:

1. Turn the device over and place it on a softpad.
2. Remove the bottom flap.
3. Turn the valve cover to the left and lift it off.
4. Replace the valve membrane with a new one. Make sure it is placed into the correct position!
5. Reinstall the valve cover and the bottom flap.

3.5 CARRY OUT MAINTENANCE 1

When?	Replacement parts	Equipment
Annually	For CARAT I pro: Maintenance kit 1a (Art.-No. 00004991) • 2x valve membranes • 2x O-rings • 1x course filter • 1x fine filter • 1x tubing set CARAT I pro For CARAT II pro: Maintenance kit 1b (Art.-No. 00004992) • 2x valve membranes • 2x O-rings • 1x course filter • 1x fine filter • 1x tubing set CARAT II pro	• Long screwdriver (PH1x200) • Needle nose pliers • M14x1 socket wrench • Softpad • Pressure meter • APM blind plug • Therapy tube with pressure measuring tube • Adapter bacterial filter (CARAT II pro)



3.5.1 WHAT NEEDS TO BE DONE DURING MAINTENANCE 1?

1. Replace valve membranes and o-rings for inspiration and expiration → Page 53
2. Replace course and fine filter → Page 52
3. Replace Silicon tubing in accordance with the tube connection diagram (starting on Page 30)
4. Visual inspection

4.1. Check tubes and tube connections

4.2. Check cables and plug connections

4.3. Check fit of all printed circuit boards

5. Calibrate the device

5.1. Calibrate the pressure sensor

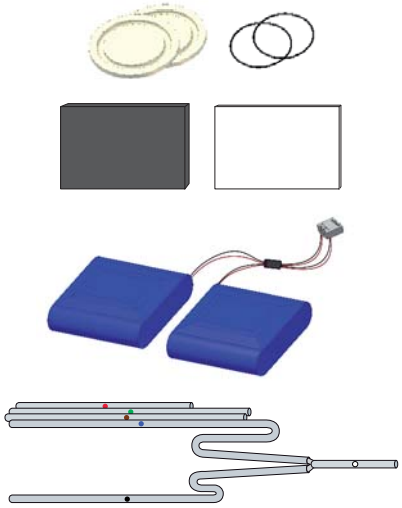
5.2. Calibrate the flow sensor (only CARAT II pro)

5.3. Tightness check

6. Perform safety-related check (see Page 69)
7. Check the electrical safety of the external power supply (see Page 67)

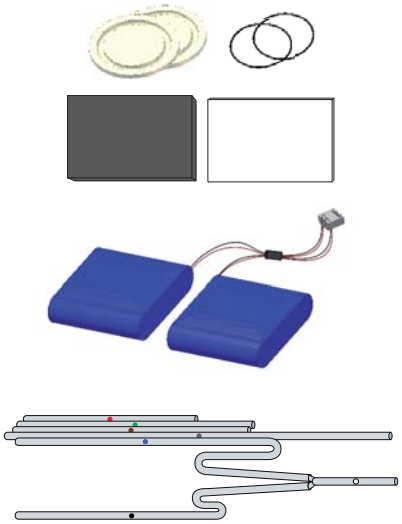
3.6 CARRY OUT MAINTENANCE 2

When?	Replacement parts	Equipment
Every 2 years	For CARAT I pro: Maintenance kit 2 a (Art.-No. 00004993) • 2x valve membranes • 2x O-rings • 1x course filter • 1x fine filter • 1x tubing set CARAT I pro • 1x ready-made battery pack (Li-Ion)	• Long screwdriver (PH1x200) • Needle nose pliers • M14x1 socket wrench • Softpad • Pressure meter • APM blind plug • Therapy tube with pressure measuring tube • Adapter bacterial filter (CARAT II pro)



For CARAT II pro:
Maintenance kit 2b
(Art.-No. 00004494)

- 2x valve membranes
- 2x O-rings
- 1x course filter
- 1x fine filter
- 1x tubing set CARAT II pro
- 1x ready-made battery pack (Li-Ion)



3.6.1 WHAT NEEDS TO BE DONE DURING MAINTENANCE 2

1. Replacing valve membranes and o-rings for inspiration and expiration → Page 53
2. Replace course and fine filter→ Page 52
3. Replace silicon tubing in accordance with the tube connection diagram (starting on Page 30).
4. Replace the battery pack
5. Visual inspection

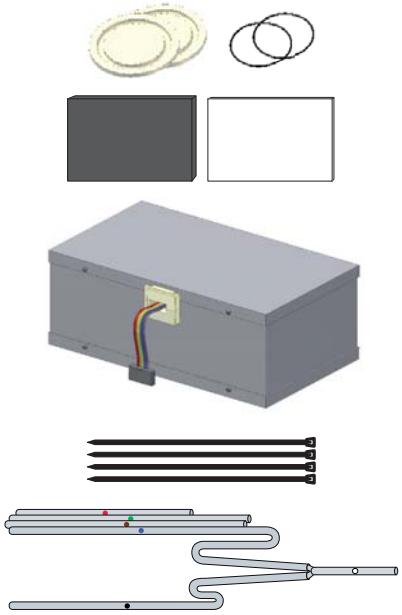
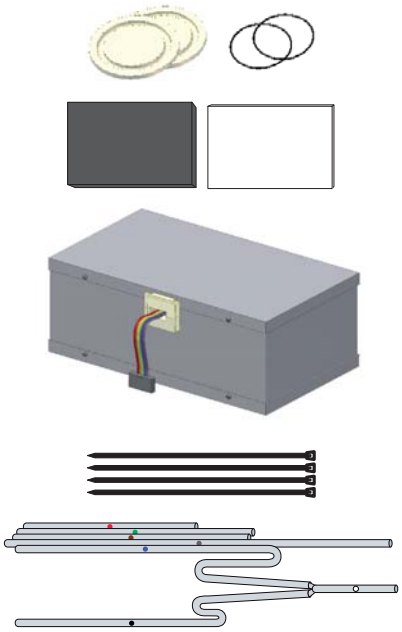
5.1. Check tubes and tube connections
5.2. Check cables and plug connections
5.3. Check fit of all printed circuit boards

6. Calibrate the device

6.1. Calibrate the pressure sensor
6.2. Calibrate the flow sensor (only CARAT II pro)
6.3. Tightness check
6.4. Battery check

7. Perform safety-related check (see Page 69)
8. Check the electrical safety of the external power supply (see Page 67)

3.7 CARRY OUT MAINTENANCE 5

When?	Replacement parts		Equipment
Every 15,000 h blower run time or every 5 years	For CARAT I pro: Maintenance kit 5 a (Art.-No. 00004995) • 2x valve membranes • 2x O-rings • 1x course filter • 1x fine filter • 1x tubing set CARAT I pro • 1x blower box • 4x cable ties (71 mm)		• Long screwdriver (PH1x200) • Wire cutters • Needle nose pliers • M14x1 socket wrench • Softpad • Pressure meter • APM blind plug • Therapy tube with pressure measuring tube • Adapter bacterial filter (CARAT II pro)
	For CARAT II pro: Maintenance kit 5b (Art.-No. 00004996) • 2x valve membranes • 2x O-rings • 1x course filter • 1x fine filter • 1x tubing set CARAT II pro • 1x blower box • 4x cable ties (71 mm)		

3.7.1 WHAT NEEDS TO BE DONE DURING MAINTENANCE 5?

1. Replacing valve membranes and o-rings for inspiration and expiration → Page 53
2. Replace course and fine filter→ Page 52
3. Replace silicon tubing in accordance with the tube connection diagram (starting on Page 30).
4. Replace blower box
5. Visual inspection

5.1. Check tubes and tube connections
5.2. Check cables and plug connections
5.3. Check fit of all printed circuit boards

6. Calibrate the device

6.1. Calibrate the pressure sensor
6.2. Calibrate the flow sensor (only CARAT II pro)

6.3. Tightness check

7. Perform safety-related check (see Page 69)
8. Check the electrical safety of the external power supply (see Page 67)

3.8 BATTERY CARE

3.8.1 PERFORM THE BATTERY QUICK TEST

The battery quick test verifies whether the device in case of a power failure can be operated on battery for at least one hour. When the device is used the battery quick test must be performed out by the provider or user every 6 months. However, a monthly check is recommended.

1. Make sure that the batteries are fully charged (100%).
2. Disconnect the device from the mains and operate the device for 1 hour on battery power.
3. The test is positive if after 1 hour the battery capacity is > 10 % and the alarm "Low Internal Battery" has not sounded. If the battery capacity has fallen below 10 % and the alarm "Low Internal Battery" has sounded, the batteries must be replaced by an authorized service technician.
4. Charge the batteries up to 100 % by operating the devices via mains.

3.8.2 CHARGING THE BATTERIES

During storage, charge the batteries every 6 months up to 100 % capacity, by operating the devices via mains supply.

CHAPTER 4

CALIBRATIONS AND TESTS

⚠ CAUTION

After each maintenance and repair session is completed, all calibrations have to be performed.

4.1 THE SERVICE SCREEN IN THE CARAT pro

The following calibrations and tests may be performed in the Service Screen environment; changing the PIN code and reset the device to the factory settings.

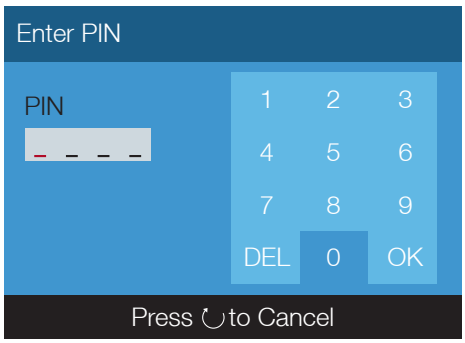
Menu item	Explanation
Calibrate Pressure Sensor	Calibration of the pressure sensor
Calibrating Flow Sensor (only on CARAT II pro)	Calibration of the flow sensor
Calibrate O_2 sensor	Calibrating the FiO_2 sensor
Calibrate Tube	Calibration of the connected tube circuit (only for tube circuits without pressure measuring tube)
Battery Check	You can carry out the battery check here.
O_2 Valve Check	You can check the oxygen valve by performing the O_2 valve test here.
Tightness Check	You can check the tube circuit by performing the tightness check here.
Change PIN	To change the PIN code
Factory Settings	To reset all settings to the factory defaults (see Page 72).

This will take you to the service screen:

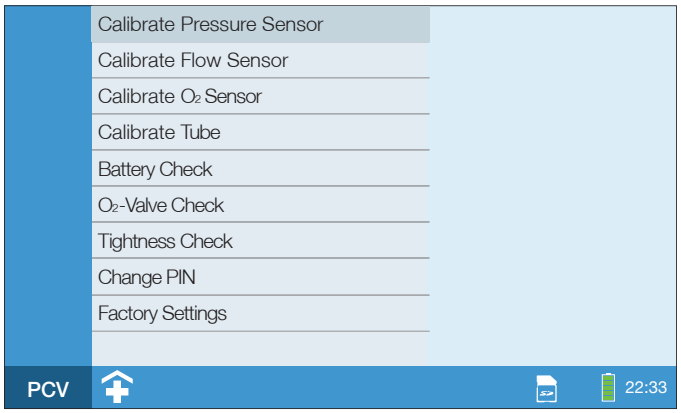
1. Navigate to "Service" in the home screen.

2. Press the MFK.

3. Enter the PIN code "1302".



4. Navigate to the desired menu item by turning the multifunctional key (MFK).



NOTE: The device will switch back to the home screen 2 minutes after the last performed operation.

4.2 CALIBRATE THE PRESSURE SENSOR

When?	Equipment
• After each repair and maintenance	• Pressure meter • APM blind plug

To perform the pressure sensor calibration:

1. Connect the pressure meter and the CARAT pro according to Figure 27.

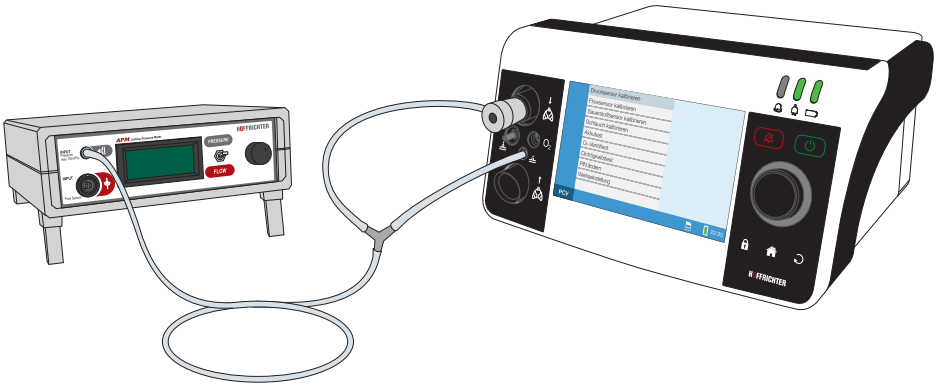


Figure 27: System configuration of pressure sensor calibration (system configuration for CARAT I pro and CARAT II pro is identical)

2. Navigate to "Calibrate Pressure Sensor" by turning the MFK.

Calibrate Pressure Sensor
Calibrate Flow Sensor
Calibrate O_2 Sensor
Calibrate Tube
Battery Check
O_2-Valve Check
Tightness Check

3. Press the MFK.

4. Press the MFK again to start measuring at 0 hPa. Turn the MFK until the pressure meter displays the pressure value of 5 hPa. The value at the pressure meter must be set with an accuracy of ± 0,05 hPa.

   Press the MFK.

Calibrate Pressure Sensor	0 hPa	0
Calibrate Flow Sensor	5 hPa	
Calibrate O_2 Sensor	10 hPa	
Calibrate Tube	20 hPa	
Battery Check	40 hPa	
O_2-Valve Check		
Tightness Check		

5. Repeat the calibration for 10 hPa, 20 hPa and 40 hPa.
   Press the escape key to cancel the pressure sensor calibration .

6. "Finish calibration" will appear after the calibration has been completed. Press the MFK to confirm the calibration.

   In case of an error message, repeat the calibration. If the calibration should fail again, contact the HOFFRICHTER service department.

   Press the MFK to stop the pressure sensor calibration.

Calibrate Pressure Sensor	0 hPa	0	Ok
Calibrate Flow Sensor	5 hPa	-1	Ok
Calibrate O_2 Sensor	10 hPa	-2	Ok
Calibrate Tube	20 hPa	1	Ok
Battery Check	40 hPa	-1	Ok
O_2-Valve Check	Finish calibration		
Tightness Check			

4.3 CALIBRATE THE FLOW SENSOR

When?	Equipment
• After each repair and maintenance	• Pressure/Flow meter with flow sensor • Therapy tube with pressure measuring tube • Adapter bacterial filter (CARAT II pro)

With the flow sensor calibration you calibrate the flow sensor (CARAT I pro) or the two flow sensors (CARAT II pro).

To perform the flow sensor calibration:

1. Set up the system according to Figure 29 or Figure 29.

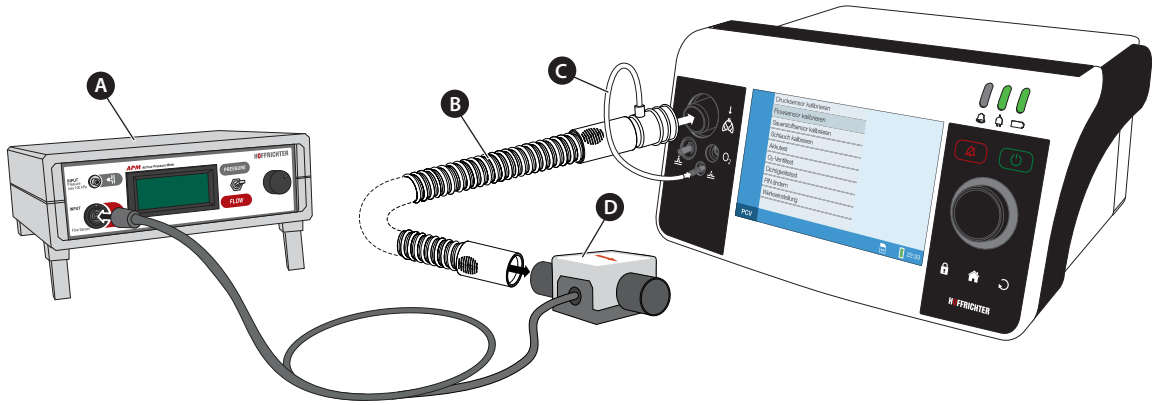
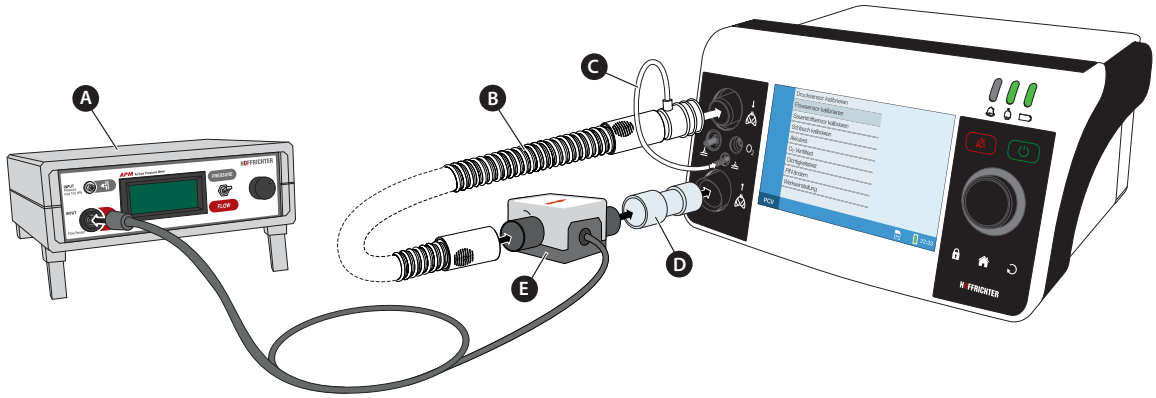


Figure 28: System configuration for CARAT I pro flow sensor calibration



A Pressure/Flow meter **B** Therapy tube **C** Pressure measuring tube **D** Adapter bacterial filter **E** Flow sensor

Figure 29: System configuration for CARAT II pro flow sensor calibration

2. Navigate to "Calibrate Flow Sensor" by turning the MFK.

Calibrate Pressure Sensor
Calibrate Flow Sensor
Calibrate O_2 Sensor
Calibrate Tube
Battery Check
O_2-Valve Check
Tightness Check
Change PIN
Factory Settings

3. Press the MFK.
The first value (0 l/min) is selected.

If you want cancel the flow sensor calibration, press the escape key .

Calibrate Pressure Sensor	0 l/min	0	Run...
Calibrate Flow Sensor	10 l/min		
Calibrate O_2 Sensor	20 l/min		
Calibrate Tube	40 l/min		
Battery Check	60 l/min		
O_2-Valve Check	80 l/min		
Tightness Check	100 l/min		
Change PIN	120 l/min		
Factory Settings	160 l/min		

4. Press the MFK.
The second value (10 l/min) is selected.
Turn the MFK as long as the calibration value is reached. The value must be set to an accuracy of ± 1.5 %. Afterwards press the MFK.
The message "OK" appears when the calibration has been done successfully.

Repeat these steps also for 20, 40, 60 80, 100, 120 and 160 l/min.

Calibrate Pressure Sensor	0 l/min	0	Ok
Calibrate Flow Sensor	10 l/min	-5	Run...
Calibrate O_2 Sensor	20 l/min		
Calibrate Tube	40 l/min		
Battery Check	60 l/min		
O_2-Valve Check	80 l/min		
Tightness Check	100 l/min		
Change PIN	120 l/min		
Factory Settings	160 l/min		

5. Press the MFK to complete the flow sensor calibration.

Calibrate Pressure Sensor	0 l/min	0	Ok
Calibrate Flow Sensor	10 l/min	-5	Ok
Calibrate O_2 Sensor	20 l/min	-18	Ok
Calibrate Tube	40 l/min	-1	Ok
Battery Check	60 l/min	126	Ok
O_2-Valve Check	80 l/min	205	Ok
Tightness Check	100 l/min	287	Ok
Change PIN	120 l/min	350	Ok
Factory Settings	160 l/min	-362	Ok
	Finish calibration		

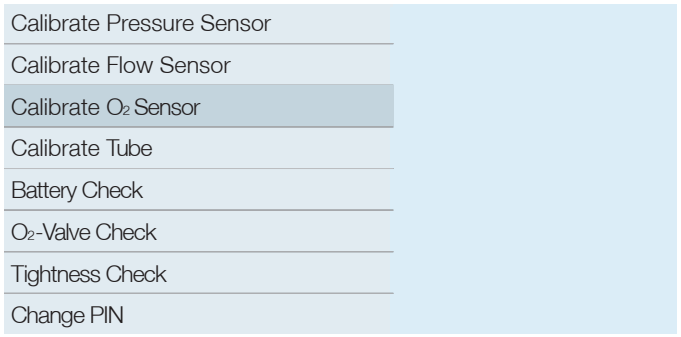
4.4 CALIBRATE THE FiO_2 SENSOR

When?	Equipment
• After each repair and maintenance	• FiO_2 sensor

Use the FiO_2 sensor calibration to check the electrical connection between the FiO_2 sensor and the device.

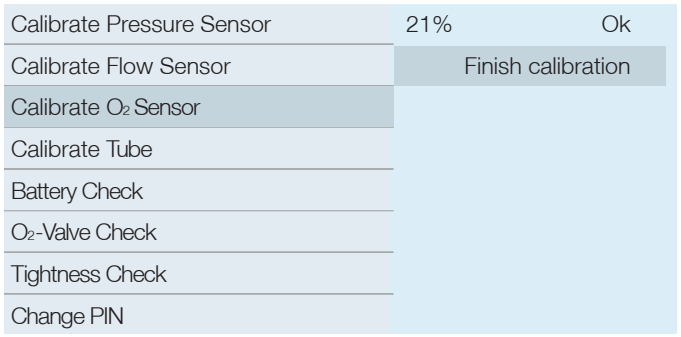
To perform the FiO_2 sensor calibration:

1. Navigate to "Calibrate FiO_2 Sensor" by turning the MFK.



2. Press the MFK.
   The FiO_2 calibration begins.

   If the calibration was successful, the word "OK" will appear after a few seconds. If the calibration should not have been successful, the word "Error" will display. In case of an error message, repeat the calibration. Should the result be unsuccessful, replace the FiO_2 sensor.



3. Press the MFK to end the FiO_2 sensor calibration.

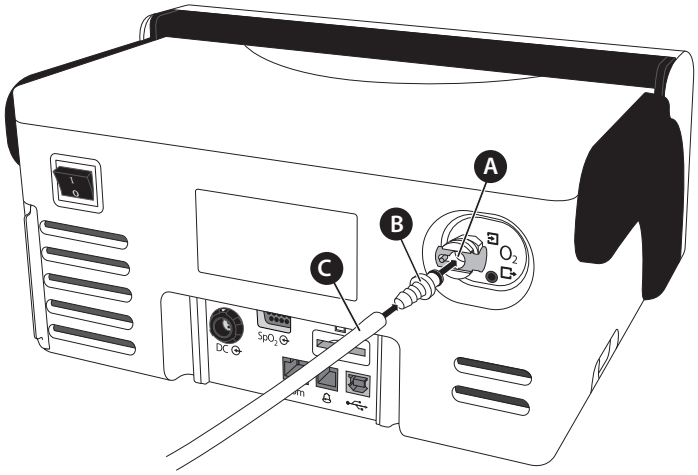
4.5 O_2 VALVE CHECK

When?	Equipment
• Annually (after each maintenance)	• Oxygen source • Straight FiO_2 connection adapter

The O_2 valve check checks if the oxygen valve is working properly.

To run the O_2 valve check:

1. Connect the oxygen source with the CARAT II pro according to Figure 30.

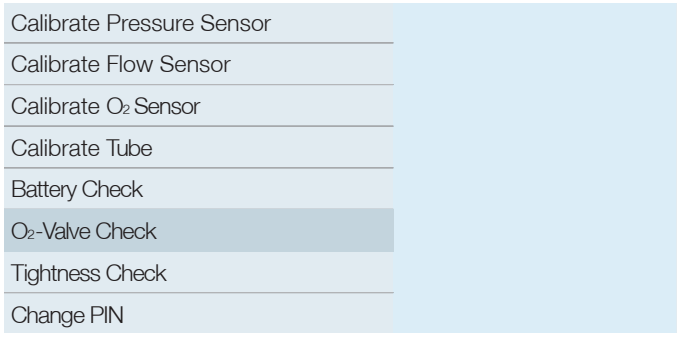


A Oxygen connection **B** Oxygen connection adapter, straight **C** Tube from the oxygen source

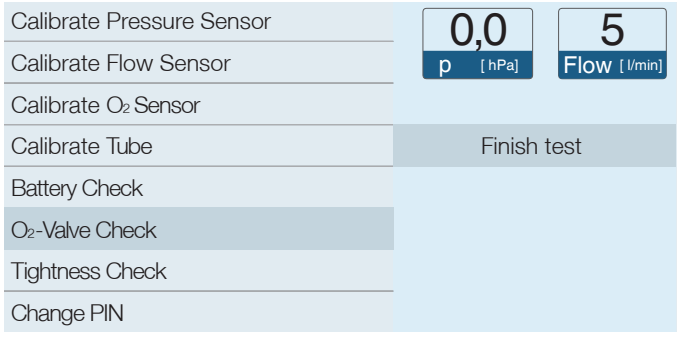
Figure 30: O_2 valve check system configuration

2. Turn on the oxygen source. Check if the fed-in oxygen is being expelled from the oxygen outlet O_2.

3. Navigate to "O_2 Valve Check" by turning the MFK.



4. Press the MFK.
   Check whether a flow is showing on the device. The flow, with which the oxygen is fed in, should match the flow in the device. If it does not, check the oxygen connecting tube and the oxygen connection point for leaks. If the values still don't match after that, do a pressure sensor calibration.



5. Press the MFK to stop the O_2 valve check.

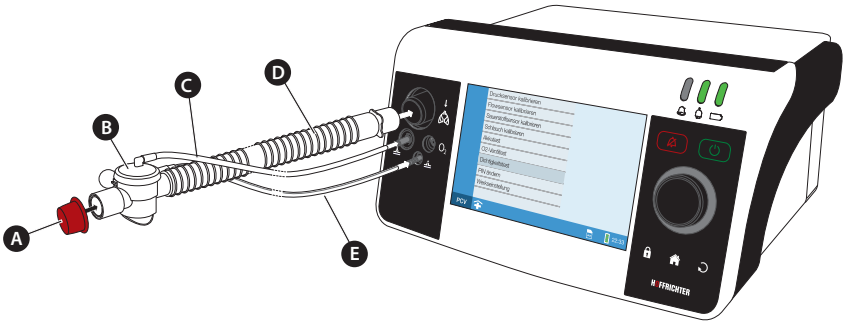
4.6 PERFORM A TIGHTNESS CHECK

When?	Equipment
• After each repair and maintenance, if a tube circuit is present	• Single line patient circuit (CARAT I pro) • Double line patient circuit (CARAT II pro) • End cap

The tightness check serves to check the tube circuit for leaks and/or damage.

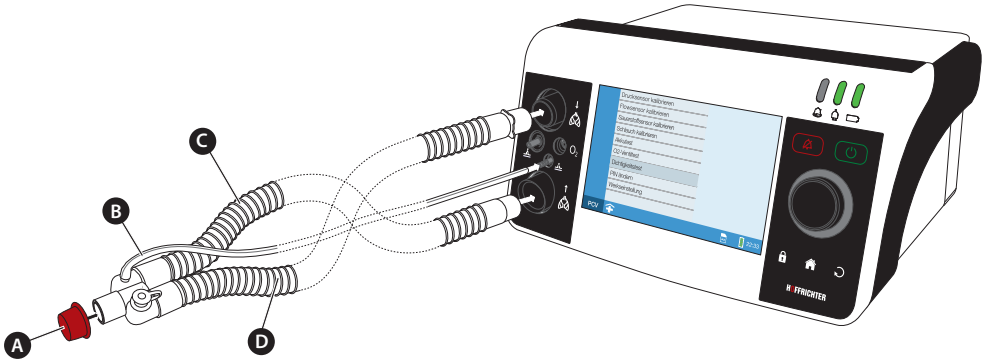
To perform the tightness check:

1. Connect the therapy tube with CARAT pro according to Figure 31 or Figure 32.



A End cap (supplied with delivery scope) **B** Expiration valve
C Control tube **D** Ventilation tube **E** Pressure measuring tube

Figure 31: System configuration for CARAT I pro tightness check

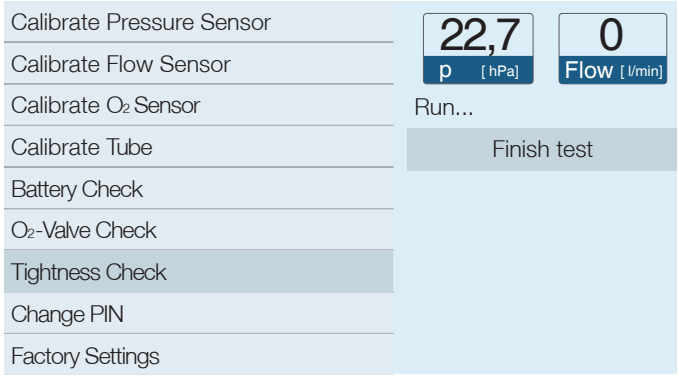


A End cap (supplied with delivery scope) **B** Pressure measuring tube **C** Expiration section **D** Inspiration section

Figure 32: System configuration for CARAT II pro tightness check

2. Navigate to "Tightness Check" by turning the MFK and press the MFK.

3. The device now scans the entire pressure range. Observe the flow value. If the flow value should exceed 5 l/min during the tightness check, there must be a leak in the tube system. In that case, check the entire system for leaks in tubes and at tube connections. As long as the flow remains under 5 l/min the tightness check has been passed successfully. Press the MFK to complete the test.



4. Press the MFK to stop the tightness check.

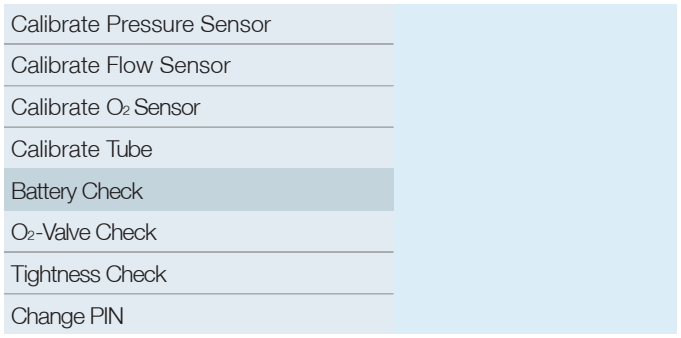
4.7 PERFORM THE BATTERY CHECK

When?	Equipment
• Maintenance 2 • After replacing the battery pack.	• Power supply unit

The battery check checks that the lithium-ion batteries in the battery pack still have sufficient capacity and whether the batteries are functioning properly. Operate the CARAT pro on the mains network and turn on the AC/main switch. No accessories such as the tube circuit should be connected at the time. Do not separate the device from the mains supply during the battery check.

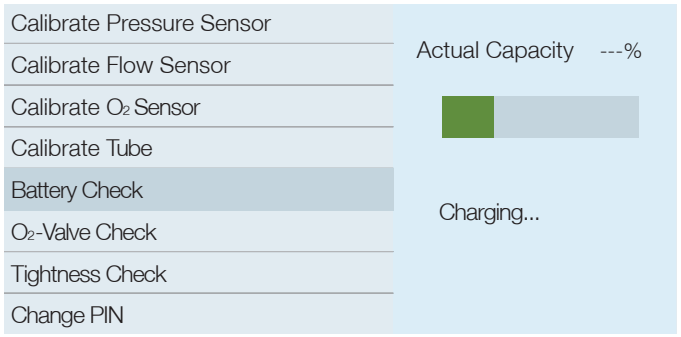
To perform the battery check:

1. Navigate to "Battery Check " by turning the MFK.

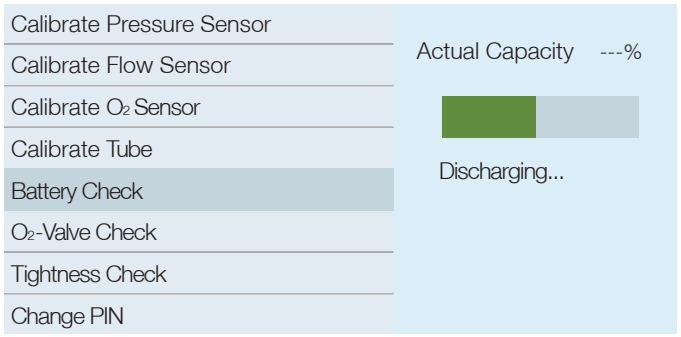


2. Press the MFK.
   During the first phase of the battery check the batteries are being recharged.

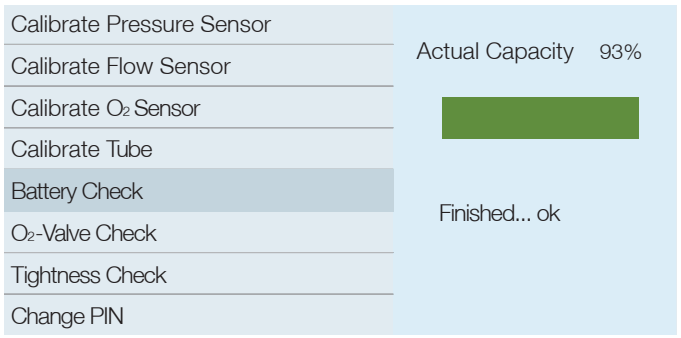
   Use the escape key to cancel the battery check.



3. In phase two the batteries are discharged at a constant load. This takes about 3 to 4 hours, depending on the battery capacity.



4. At the end of the battery check the battery capacity (actual capacity) will be displayed. The test has been passed, when the capacity is ≥ 80 %. If the capacity is lower, plus an "Error" message appears, the battery pack has to be replaced with a new one.



4.8 TEST THE POWER SUPPLY FOR ELECTRICAL SAFETY

4.8.1 TESTS

The tests are done with a device safety-related check (e.g. SECUTEST SIII), which works according to the DIN EN 62353:2008 standard. Discharge currents always have to be calculated via direct measuring. The ventilator system is to be checked according to protection category II with the application part Type BF. The associated power supply of Protection category II is checked in the system. Defects at the power supply will be detected while checking the entire system according to Protection category II.

4.8.2 DEVICE DISCHARGE CURRENT

The device discharge current is measured with a probe of the device safety-related check equipment (e.g. SECUTEST SIII) at the FiO_2 sensor connection. The test is considered passed when the limit values of the device discharge currents are within the standards of DIN EN 62353-2008, table 2.

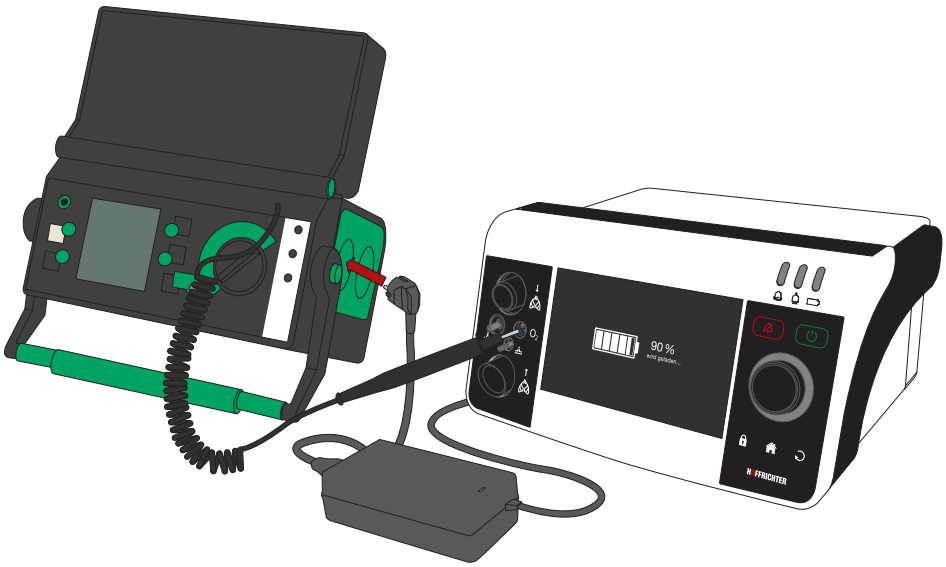


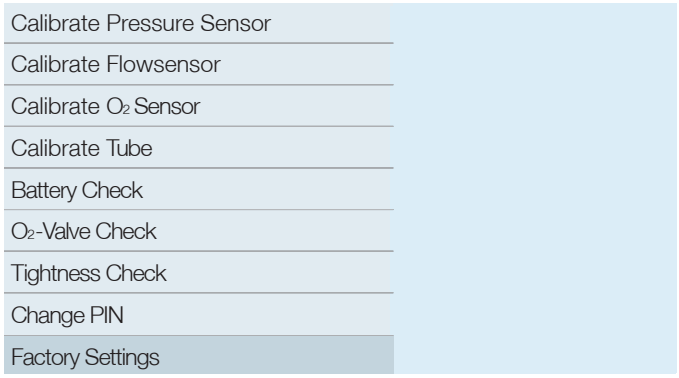
Figure 33: System configuration for measuring the device discharge current

4.9 SEND PARAMETERS

4.9.1 RESETTING THE DEVICE TO FACTORY SETTINGS

To reset the device to factory settings:

1. Turn on the main switch.
2. Navigate to "Factory Settings" by turning the MFK.



3. Press the MFK.
4. Navigate to "Yes" by turning the MFK.

5. Press the MFK.

4.9.2 SEND THE PATIENT DEVICE SETTINGS

Send the device settings for data backup to the device using the "EASYset" software (not yet available).

CHAPTER 5

PERFORM THE FINAL INSPECTION

After all calibrations and checks have been performed, the device must be checked for damage and proper functionality. The following describes the measures to be taken. Implementation of the safety-related checks are to be logged in the medical product book.

Test	Execution
Handle intact and functional	Do a visual inspection for signs of physical damage (scratches etc.). Pull the handle upwards. There must not be any noise to be heard. Check that the handle holds its position in the fully extended position.
Hardware test at device start-up	Power on the device using the AC/main switch and check if the device starts without error messages.
Operational controls are functioning properly	Check all operating elements for damage and proper function.
Check the touch pad function	Check the touch feature.
Connections intact and functional	Check all pneumatic and electrical connection points for damage and proper function.
Check display	Make sure the display is operating properly. If necessary, change the brightness.
Serial numbers, type plate and device are identical	Check that the serial number on the type plate and the serial number on the device match.
Device switches off	Shut down the ventilation, if necessary, and turn off the device via the AC/main switch. Make sure the device has been properly shut down and the standby screen is showing. Then unplug the power cord from the unit and check that the device is properly shut down.
Operation with internal battery	With the device turned on, unplug the power cord. The message "On battery" should be showing in the window.
Nurse call/remote alarm with alarm box	If a remote alarm is available: Connect an alarm box to the "Remote alarm" connection point. Then create an alarm event and check if the alarm is forwarded to the alarm box.
Device language has been selected	Check that the customer specific device language has been selected. If not, change the language on the system screen.
Safety-related check	
Physical damage to the device exterior?	Check if the device shows signs of damage.
Damage to the accessories?	If applicable, check the accessories for damage.
"Check Expiration Outlet" and "Stenosis" alarm	CARAT I pro 1. Start ventilation setting the PCV mode. 2. Select the screen "Alarm Log". 3. Close up the tube at the patient connection side. 4. After 3 breaths the alarms "Stenosis" and then "Check Expiration Outlet" must appear. CARAT II pro "Stenosis" 1. Start ventilation setting the PCV mode. 2. Select the screen "Alarm Log". 3. Disconnect the inspiration tube from the device and close up the inspiration port of the device. 4. After 3 breaths the alarm "Stenosis" must appear.

Test	Execution
	"Check Expiration Outlet" 1. Start ventilation setting the PCV mode. 2. Select the screen "Alarm Log". 3. Disconnect the expiration tube from the device and close up the expiration tube at the device connection side. 4. After 3 breaths the alarm "Check Expiration Outlet" must appear.
"Check Measuring Tube" alarm	To simulate a "Check Measuring Tube" alarm, a tube circuit with a measuring tube is required. CARAT I pro und CARAT II pro 1. Start ventilation setting the PCV mode. 2. Disconnect the pressure measuring tube from the device. 3. The "Check Measuring Tube" alarm must appear after about 3 s.

CHAPTER 6
APPENDIX

6.1 ERROR LIST

Table 2: Error messages during operation and at device start-up

Error message	Cause	Correction
Error SpO_2 sensor	Communication with SpO_2 measuring module not possible	Device must be serviced
	SpO_2 sensor defective	Replace SpO_2 sensor
SD card is full	No storage space available on the SD card	Insert blank SD card
Flash Not Working	No access to the flash	Device must be serviced
An older parameter set is on the device	Current parameter set is incorrect	The device uses the old parameter set and can continue to be utilized.
Default parameters are on the device	No valid parameter set available or they are faulty	The device uses the efault parameter set and can continue to be utilized.
The flow sensor shows an error	Flow sensor is defective	Device must be serviced
The FiO_2 sensor shows an error	FiO_2 sensor is defective	Check FiO_2 sensor connection
		Recalibrate FiO_2sensor
		Replace FiO_2 sensor
Error Pressure Sensor	Defective pressure sensor	Device must be serviced
Calibration File Damaged	Calibration data for sensors is damaged	Device must be serviced
Eventlog File Damaged	Event read data failed	Device must be serviced
Primary Alarm Not Working	Primary alarm sound unit is defective	Device must be serviced
Secondary Alarm Not Working	Secondary alarm sound unit is defective	Device must be serviced
No Alarm Available	Primary and secondary alarm sound units are defective	Device must be serviced
Booting Error	Boot failed	Device must be serviced
Fatal Error	Fatal error occurred	Device must be serviced
Maintenance 5 necessary	Maximum blower run times reached	Device must be serviced

6.2 FACTORY SETTINGS

6.2.1 VENTILATION PARAMETERS

Table 3: Default settings for ventilation parameter

	Mode								
Parameter	PCV (Set 1)	PSV (Set 2)	P-SIMV (Set 3)	APCV	PSV-S	VCV	AVCV	V-SIMV	CPAP
Pressure	-	-	-	-	-	-	-	-	4 hPa
IPAP	20 hPa	20 hPa	20 hPa	20 hPa	20 hPa	-	-	-	-
PS	-	-	20 hPa	-	-	-	-	20 hPa	-
Tidal Volume	-	-	-	-	-	0.05 l	0.05 l	0.05 l	-
PEEP	5 hPa	5 hPa	5 hPa	5 hPa	5 hPa	5 hPa	5 hPa	5 hPa	-
Frequency	12 bpm	12 bpm	12 bpm	12 bpm	-	12 bpm	12 bpm	12 bpm	-
Time Inspiration	2 s	2 s	2 s	2 s	-	2 s	2 s	2 s	-
Flow Ramp	-	-	-	-	-	1	1	1	-
Max. Pressure	-	-	-	-	-	30 hPa	30 hPa	30 hPa	-
Min. Pressure	-	-	-	-	-	10 hPa	10 hPa	10 hPa	-
Ti Max	-	4 s	4 s	-	4 s	-	-	4 s	-
Ti Min	-	0.4 s	0.4 s	-	0.4 s	-	-	0.4 s	-
Apnoea Time	-	10 s	-	-	-	-	-	-	-
Ramp	3	3	3	3	3	-	-	3	-
Inspiration Trigger	-	3	3	3	3	-	3	3	-
Expiration Trigger	-	30 %	30 %	-	30 %	-	-	30 %	-
Trigger Lock	-	Off	Off	Off	Off	-	Off	Off	-
Minimum Volume	Off	Off	-	Off	Off	-	-	-	-
Sigh Function	Off	Off	Off	Off	Off	Off	Off	Off	-

6.2.2 ALARM PARAMETERS

Table 4: Default/factory settings for alarm parameter

	Mode								
Parameter	PCV (Set 1)	PCV (Set 2)	P-SIMV (Set 3)	APCV	PSV-S	VCV	AVCV	V-SIMV	CPAP
Apnoea Alarm	-	-	-	-	10 s	-	-	-	10 s
High Frequency	-	30 bpm	30 bpm	30 bpm	30 bpm	-	30 bpm	30 bpm	30 bpm
Low Frequency	-	Off	-	-	Off	-	-	-	Off
High Inspiration Volume	1 l	1 l	1 l	1 l	1 l	Off	-	-	1 l
Low Inspiration Volume	0.2 l	0.2 l	0.2 l	0.2 l	0.2 l	Off	-	-	0.2 l
High Minute Volume	Off	Off	Off	Off	Off	Off	Off	Off	Off
Low Minute Volume	Off	Off	Off	Off	Off	Off	Off	Off	Off
Leak Rate	Off	Off	Off	Off	Off	Off	Off	Off	Off
High FiO_2	Off	Off	Off	Off	Off	Off	Off	Off	Off
Low FiO_2	Off	Off	Off	Off	Off	Off	Off	Off	Off
Low SpO_2	Off	Off	Off	Off	Off	Off	Off	Off	Off
Pos. Pressure Tolerance	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa
Neg. Pressure Tolerance	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa	3 hPa

6.2.3 DEVICE PARAMETERS

Table 5: Default settings for device parameters

Parameter	Factory setting	Setting range	Setting steps
FiO_2-Monitoring	Internal	internal, external	-
Alarm Volume	3	1 – 3	1
Brightness Display	100 %	5 – 100 %	5 %
Brightness LEDs	100 %	5 – 100 %	5 %
Brightness MFK	100 %	5 – 100 %	5 %
Language	English	German, English and others	-
Pressure Unit	hPa	hPa, mbar, cmH_2O	-
Display Time Insp.	s	s, I:E	-
Number Ventilation Sets	3	1 – 3	1

6.3 REPLACEMENT PARTS LIST

Table 6: Replacement parts list

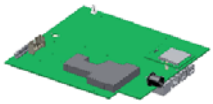
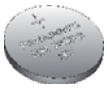
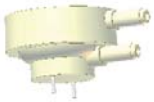
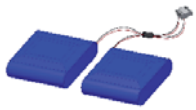
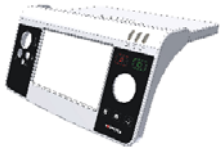
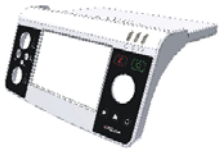
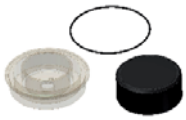
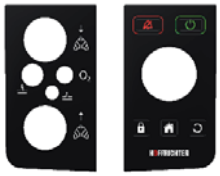
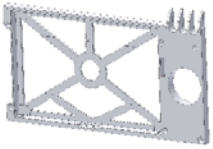
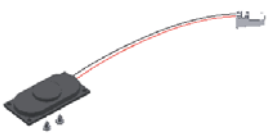
Name Article number	Figure	Name Article number	Figure
Controller circuit board 00004146		Operating Circuit Board 00004147	
Encoder 21000017		Lithium cell CR2032 (3 V) for clock function 16000004	
60 mbar over pressure trigger 00014156		LP SD card module 25200122	
Piezo signal head with 2 expansion rivets 00004339		Ready-made battery pack (Li-Ion) 00004129	
Battery holder 42101307		CARAT I pro top cover (without operating circuit board, without display frame, without display) 00004169	
CARAT II pro top cover (without operating circuit board, without display frame, without display) 00004170		7" display 15200021	
Multifunction key (consisting of rotary knob, cover, input rotary knob, circlip, o-ring) 00004150		CARAT I pro foil set 22000228	
CARAT II pro foil set 22000227		Display frame 42101311	
Right trim handle + 3 screws without speaker 00004131		Left trim handle + 3 screws 00004132	
Speaker + screws 00004134		Replacement handle + screws 00004174	

Table 6: Replacement parts list

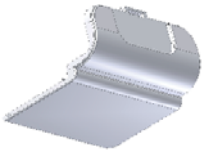
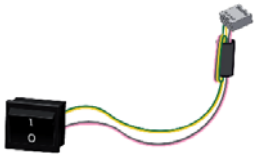
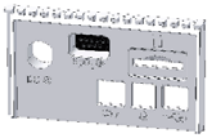
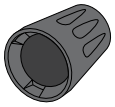
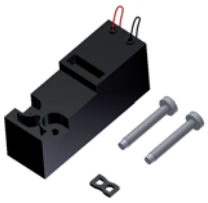
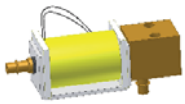
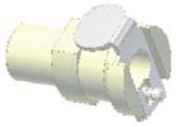
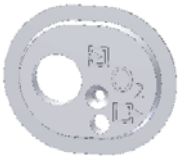
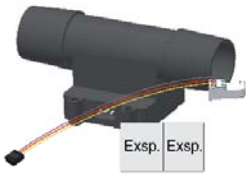
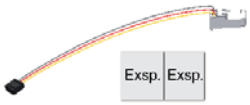
Name Article number	Figure	Name Article number	Figure
Bottom flap 42101304		Mounted main switch 00004156	
Rubber feet (4 pieces) 00004175		Ready made interface plate (with SpO2 bushing and cable) 00004165	
M14x1 socket wrench 00004130		Front nut for DC connection 43000114	
(12 V) proportional valve with screws, seal and bushing strip 23000039		3/2-way valve with fasteners, seal and bushing strip 00004273	
Control tube valve CARAT II pro (2/2-way valve) with screws and bushing strip 00004178		Oxygen block 42100447	
Oxygen adapter (internal) 42101310		FiO_2-coupling 41000086	
FiO_2 adapter baffle 42101314		Flow sensor (waterproof) with cable 23000041	
Flow sensor cable 00004135		Flow sensor seal 42100440	
CARAT pro sensor block without flow sensors 00004180		CARAT I pro tube connector 00004159	

Table 6: Replacement parts list

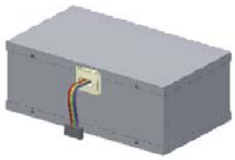
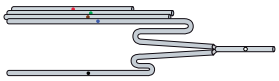
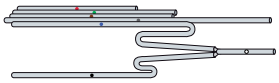
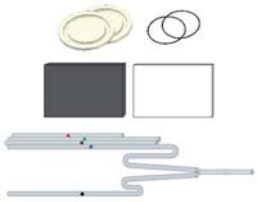
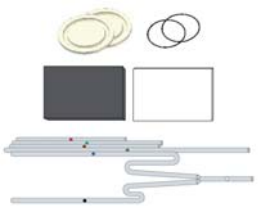
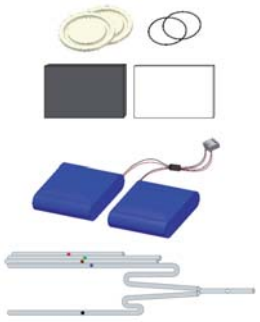
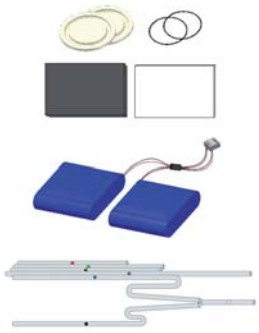
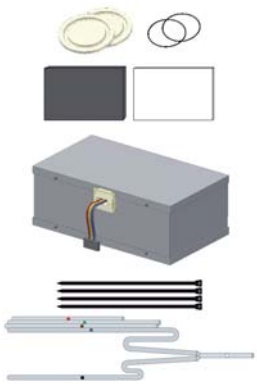
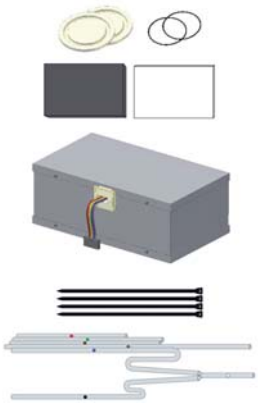
Name Article number	Figure	Name Article number	Figure
CARAT II pro tube connector 00004160		Support frame (for tube connection seal) 42101317	
Tube connection seals 42101312		Blower box 00004505	
Seal for air outlet CARAT (box) 42100424		30x1.2 O-ring 44000068	
Valve membrane 42100423		Valve cover 00004530	
FiO_2 sensor bushing replacement kit 00004988		CARAT pro air outlet 42100454	
CARAT I pro tubing set 00004167		CARAT II pro tubing set 00004168	
CARAT I pro maintenance kit 1a 00004991		CARAT II pro maintenance kit 1b 00004992	
CARAT I pro maintenance kit 2 a 00004993		CARAT II pro maintenance kit 2b 00004994	

Table 6: Replacement parts list

Name Article number	Figure	Name Article number	Figure
CARAT I pro maintenance kit 5 a 00004995		CARAT II pro maintenance kit 5b 00004996	
Reconditioning Kit 1 for CARAT I pro 00004997		Reconditioning Kit 2 for CARAT II pro 00004998	
Membrane replacement kit 00004990			

6.4 ACCESSORY LIST

Table 7: Accessory list

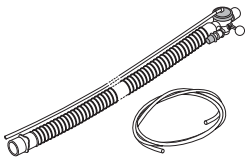
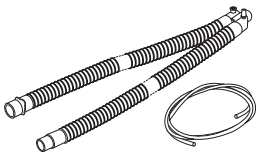
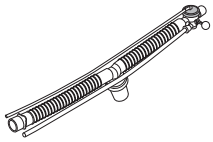
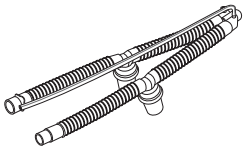
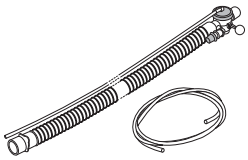
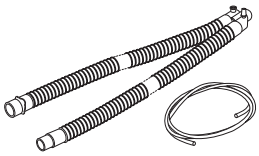
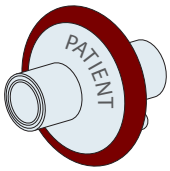
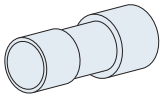
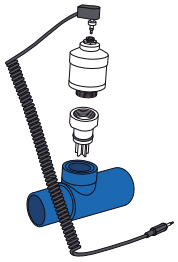
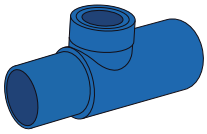
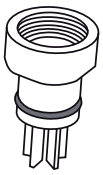
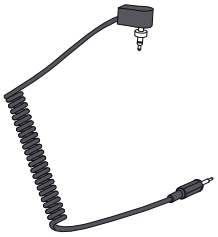
Name Article number	Figure	Name Article number	Figure
Disposable single line patient circuit for adults with expiratory valve and pressure measurement and control tube (L = 180 cm, ∅ 22 mm) 00014967		Disposable double line patient circuit for adults with pressure measuring tube (L = 180 cm, ∅ 22 mm) 00007969	
Disposable single line patient circuit for adults with expiratory valve and pressure measurement and control tube plus water trap (L = 180 cm, ∅ 22 mm) 00014995		Disposable double line patient circuit for adults with pressure measuring tube and water traps (L = 180 cm, ∅ 22 mm) 00007996	
Disposable single line patient circuit for children with expiratory valve, pressure measurement and control tube (L = 180 cm, ∅ 15 mm) 00014923		Disposable double line patient circuit for children with pressure measuring tube (L = 180 cm, ∅ 15 mm) 00004928	
Bacterial filters 00004932		Bacterial filter adapter 00004933	
FiO_2 measurement set consisting of: FiO_2 sensor, T adapter FiO_2 sensor-adapter, connection cable, FiO_2 sensor with screw connection 00004944		FiO_2 sensor OOM103-1 23000018	
T adapter 23000019		Housing gas line FiO_2 sensor connector piece 23000020	
FiO_2 sensor connecting cable with screw terminal 00014116		FiO_2 connection adapter, angled 41000087	

Table 7: Accessory list

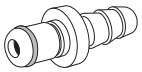
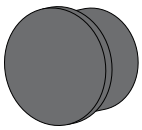
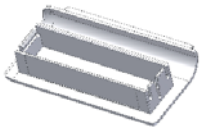
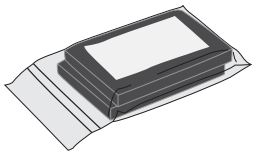
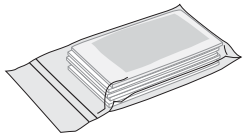
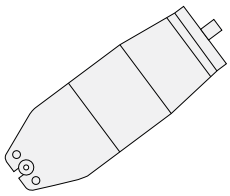
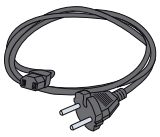
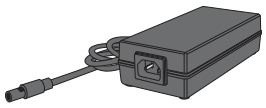
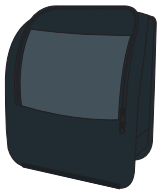
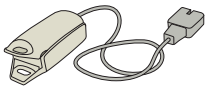
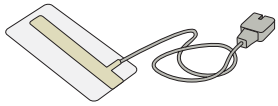
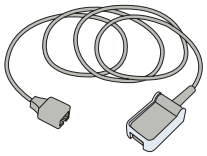
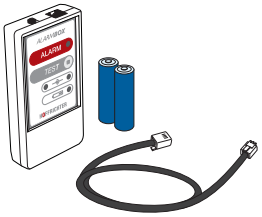
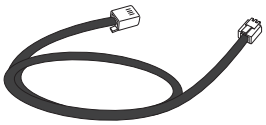
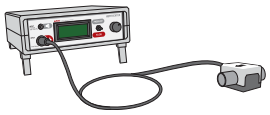
Name Article number	Figure	Name Article number	Figure
FiO_2 connection adapter, straight 41000104		Aperture for expiration tube connection 42100449	
Filter cassette, complete (open) 00002145		Filter cassette, complete (closed) 00002146	
Filter cassette (open) with filters 00002038		Filter cassette (closed) with filters 00002058	
Filter cassette cover 42101302		Coarse filter, 1 pack (2 ea) 00014950	
Fine filter, 1 pack (5 ea) 00014951		Test lung 00004960	
USB cable (PC cable) 00005291		SD card 11200010	
Power cord 31100023		Switched-mode power supply 00014206	
Carrying case 00004875		Functional bag 00004879	
SpO_2 finger clip sensor, cable length 2 m 00005292		SpO_2 adhesive sensor for adults and children (finger and toe), cable length 2 m 00005294	

Table 7: Accessory list

Name Article number	Figure	Name Article number	Figure
Extension cable for SpO_2 sensor, cable length 1 m 00005293			
Brief instructions for CARAT I pro 50000613		Brief instructions for CARAT II pro 50000645	
User's manual for CARAT I pro for physicians and medical professionals 50000611		User's manual for CARAT I pro for patients 50000612	
User's manual for CARAT II pro for physicians and medical professionals 50000625		User's manual for CARAT II pro for patients 50000626	
Service manual 50000650		Hygiene concept 50000652	
Alarm box including cable and batteries 00014122		Alarm box 00004834	
Cable for alarm box 00014115		APM airflow pressure meter incl. accessories 00004040	
PC software "EASYset"			

6.5 DISPOSAL

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

6.5.1 DEVICE AND COMPONENTS

The device or components must not be disposed of with the household waste. They must be disposed of at a communal collection point or public waste-disposal authority.

6.5.2 PACKAGING

The packaging can be disposed with the normal household waste.

6.5.3 BATTERIES

Batteries must not be disposed of with the household waste. They must be disposed of at a local retailer or at a communal collection point.

6.5.4 FiO_2 SENSOR

The FiO_2 sensor must not be disposed of with the household waste. It should be disposed of correctly by incineration in a hazardous waste incineration plant. Local official regulations should be observed.

6.6 SHIPPING INSTRUCTIONS

6.6.1 SHIPPING INSTRUCTIONS FOR CONTAMINATED MEDICAL TECHNOLOGY

The following shipping instructions apply to contaminated medical technology which is delivered to HOFFRICHTER GmbH for processing.

6.6.2 PICK-UP

The dealer, medical technician or authorised personnel picks up the contaminated medical technology from the patient. A local surface disinfection of the equipment and accessories with microcide liquid spray (MRSA active) takes place followed by carefully placing the objects in bags with the use of disposable gloves, mask and disposable apron. The proper disposal of disposable materials is respected.

6.6.3 PACKAGING FOR SHIPPING

The packaging of equipment/accessories in sterile welding foil followed by shrink wrap or packing in PVC or PE bags (tear resistant) and sealed by tape or tie wrap takes place at the dealer's or in the service departments. Power cable, ventilation equipment, user's manual and other accessories with minimal risk of infection must be properly disposed of.

Hint: "CAUTION – CONTAMINATED EQUIPMENT'" or
"CAUTION – MRSA-CONTAMINATED EQUIPMENT'"
must be visibly placed on the packaging.

The packaging must be proper and robust and **must not be contaminated**. The box is conscientiously sealed with packing tape.

6.6.4 SHIPPING

The delivery note must be on the outside of the equipment packaging.
(Notice on delivery note: "CAUTION – CONTAMINATED EQUIPMENT" or "CAUTION - MRSA-CONTAMINATED EQUIPMENT"). Shipping takes place by appropriate logistics companies.

6.6.5 SHIPPING DEVICES AFTER MAINTENANCE OR REPAIRS

The shipping instructions apply to medical technology, which is sent back to the customer or dealer by the Service department, after maintenance or repairs.

6.6.6 PACKAGING FOR SHIPPING

The device is packaged in PVC or PE bags (tear proof). The bag must be sealed securely (e.g., tape or cable ties). The packaging must be proper and robust and **must not be contaminated**. The box should be sealed carefully with packing tape.

6.6.7 SHIPPING

The accompanying documents must contain the following information, which must be visible to the recipient:

> **Zu Ihrer Information!**
> Dieses Gerät wurde nur oberflächendesinfiziert. Es erfolgte keine hygienische Aufbereitung.
>
> **For your information!**
> This device was disinfected only at the surface. There was no hygienic treatment.

Shipping takes place by appropriate logistics companies.